

**CLEAN AIR ACT: OZONE AND PARTICULATE
MATTER STANDARDS**

HEARINGS
BEFORE THE
SUBCOMMITTEE ON
CLEAN AIR, WETLANDS, PRIVATE PROPERTY AND
NUCLEAR SAFETY
AND THE
COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE
ONE HUNDRED FIFTH CONGRESS
FIRST SESSION
—
FEBRUARY 5 AND 12, 1997
AND
MARCH 3, 1997—OKLAHOMA CITY, OK
—

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CLEAN AIR ACT: OZONE AND PARTICULATE MATTER STANDARDS

WEDNESDAY, FEBRUARY 5, 1997

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON CLEAN AIR, WETLANDS,
PRIVATE PROPERTY AND NUCLEAR SAFETY,
Washington, DC.

REVIEW OF THE SCIENCE

The subcommittee met, pursuant to notice, at 9:37 a.m., in room 406, Senate Dirksen Building, Hon. James M. Inhofe (chairman of the subcommittee) presiding.

Present: Senators Inhofe, Hutchinson, Allard, Sessions, Graham, Lieberman, Boxer, and Chafee [ex officio].

Also present: Senators Baucus and Thomas.

OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator INHOFE. This hearing will now come to order.

As the new chairman of the Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety of the Environment and Public Works Committee, I would like to welcome everyone to our first hearing of the 105th Congress. Today's hearing will look at the EPA's newly proposed ozone and particulate matter standards. I want to impress upon everyone that we are here to make sure that we have one thing in common: we want good air to breathe. I want it for the people in this room, for my kids, and for my grandchildren. That's what this is all about.

It is my intention to run this hearing in a balanced and thoughtful manner. The witnesses for this hearing—and this will hold for all future hearings—have been carefully selected to provide a complete spectrum of diverse viewpoints. In particular, we have invited the principal researchers the EPA relied upon in their proposal, as well as the chairman of CASAC—the Clean Air Scientific Advisory Committee. There are 21 members of this committee.

Some of today's witnesses have already been criticized by environmental groups for their ties to industry, in particular Dr. Wolff, the chairman of CASAC. I want to extend my apologies to Dr. Wolff for having his character impugned in this manner. I want to make it very clear that he is not testifying today because of his occupation, but because he is the appointed chairman of the Administrator's Clean Air Scientific Advisory Committee.

The purpose of this hearing is to address the scientific questions behind the recent EPA proposals to change the national ambient air quality standards for ozone and particulate matter. We are not here today to talk about cost/benefit. We are not here today to talk about impositions on lifestyles. These are very significant issues that will be addressed in future hearings.

As the chairman of this subcommittee, I selected the science issues to bring the oversight process because I believe we owe it to the American public to help search for the facts and the truth. These are very difficult and complex scientific issues and they deserve this separate hearing, apart from other considerations, because of the importance science has in formulating and administering our Nation's environmental laws and policies.

There are a number of questions about the science that have been raised since the EPA first published these proposals. It is my hope that today's hearing can begin to answer these questions, not only for myself and the committee, but also for the American public.

First matter to determine: There is considerable confusion as to what the EPA's Clean Air Scientific Advisory Committee recommended and what they did not recommend.

Second, there are questions about which determinations made by the Administrator were based on science and which ones were based on policy judgments. While we are not going to question those policy judgments today, we need to identify which ones were based on science and which ones were not. Is the change from a 1-hour standard to an 8-hour standard for ozone justified by the available science? I have heard very little disagreement there, but I have heard disagreement concerning the specific threshold limit set. Was this a science call or was it a policy judgment?

Third, how complete is the scientific body of knowledge behind these proposals? If not, then is more time needed to conduct the appropriate studies and research?

Fourth, with a scientific review of the standards required every 5 years, are we at a point today where we can say definitively that the science requires a change in the standards, or are there still too many uncertainties and unanswered questions?

While I applaud the Agency's desire to protect the health of the American public, we must be sure that our mutual goal will, in fact, become a reality if these proposed regulations go into effect. Too often, government officials—both elected and appointed—hid behind scientists when proposing policy decisions. Congress hides behind science when it tells agencies to promulgate regulations based upon the best available science, instead of making the difficult policy decisions themselves; and administrations also hide behind science by substituting scientific statements for policy findings.

We need to let scientists tell us what the science is, but as policymakers and lawmakers, we need to take that science and determine what constitutes the best public policy decision.

Finally, I would like to say that I am pleased that the Administrator has agreed to extend the comment period by 60 days. It is very difficult during the holiday season—and since it first came up during the time of Thanksgiving—to productively use that period

of time. The EPA needs to hear from all segments of the public, and this extension will allow those people and organizations with fewer resources to spend more time analyzing the proposals. This will particularly help the States and local governments understand the proposals, which is vital since they will be instrumental in the implementation of these standards.

Senator INHOFE. I would now turn to the chairman of the parent committee, the Environment and Public Works Committee, Senator Chafee.

**OPENING STATEMENT OF HON. JOHN H. CHAFEE,
U.S. SENATOR FROM THE STATE OF RHODE ISLAND**

Senator CHAFEE. Thank you very much, Senator Inhofe. I want to commend you for holding these hearings. You have a good list of witnesses. You certainly were right when you said this was a complicated subject.

Over the past 25 years our Nation has spent more than \$450 billion to clean our air of life-threatening pollution. This effort has been a tremendous success. The most recent report card issued by the EPA indicates that pollution levels have been reduced by nearly 30 percent, on average, with even greater gains made for some of the most serious pollutants, namely lead—lead is down 98 percent, probably mostly due to the fact that we have gone to unleaded gasoline—and the reduction also in carbon monoxide, which is also significant. All of these have occurred in some of our most polluted cities.

In spite of these achievements, EPA has recently proposed new regulations that suggest we have a long way to go. These new standards for smog and soot are 25 percent to 35 percent more stringent than the current levels and would require the expenditure of tens of billions of additional dollars.

Senator Inhofe, in the subcommittee and in the full committee, we plan to conduct a thorough review of these proposals. Senator Inhofe, as I mentioned, is making an excellent start this morning. The scientists, as he pointed out, we have with us this morning include the current and past chairmen of EPA's Clean Air Scientific Advisory Committee and some of the principal investigators whose studies form the scientific foundation for these proposed standards.

I hope that all of the members of the committee on both sides come to these hearings with open minds. These are extremely complex proposals based on thousands of pages of detailed analysis. I want to commend Administrator Carol Browner for seeking an extension from the court so that all of those affected by these proposals will have more time to review and consideration. She will be with us at a hearing next Wednesday, February 12, before the full committee. She has indicated that EPA stands ready to assist us in any way that it can to help us understand these proposals.

Thank you very much, Mr. Chairman.

Senator INHOFE. Thank you, Mr. Chairman.

Next we will hear from the ranking minority member of the parent committee, Senator Baucus.

**OPENING STATEMENT OF HON. MAX BAUCUS, U.S. SENATOR
FROM THE STATE OF MONTANA**

Senator BAUCUS. Thank you, Senator.

Mr. Chairman, first I want to congratulate you on taking over your chairmanship on a very minor, inconsequential issue—

[Laughter.]

Senator BAUCUS. I admire your courage for beginning with this.

I am sure, as other Senators have mentioned, the Clean Air Act has actually been a huge success for our country. I think it may be this committee's most significant accomplishment. Since the Act became law in 1970, the population of the United States has grown by 25 percent, and the size of our economy has doubled. During the same time, our air has actually gotten cleaner, even with the increased population and our economy. In some cases, a lot cleaner.

Air pollution from carbon monoxide has fallen by 28 percent since 1970, from sulfur dioxide 41 percent, from particulates 80 percent, lead by 98 percent. A major reason for this success has been the program of National Ambient Air Quality Standards. That might sound arcane, but the basic idea is very simple. Before 1970, we had a Federal air pollution program, but it wasn't working. One reason was that air pollution standards were determined by balancing public health standards against economic policy.

The principal author of the Clean Air Act, Senator Muskie, put it this way:

The concept of economic feasibility had become an excuse for doing nothing, and we agreed that the dangers to health from dirty air were sufficiently great that regulations should be based on the degree of control needed to protect public health.

So in the Clean Air Act of 1970, Congress remedied that defect and established a two-tiered system for setting clean air standards.

In the first step, the EPA establishes national air quality standards at the level that is necessary, in the words of the statute, to "protect public health" with an "adequate margin of safety." As the second step, the States write implementation plans. When they do, they then have the flexibility to consider a variety of factors, including costs. A State can, for example, decide that it makes more sense to achieve reductions from a few large industrial sources of pollution than from a lot of small sources like dry cleaners and print shops.

Over the years, this two-step approach has kept the goal focused, unambiguously, on public health. At the same time, it has allowed States to consider costs appropriately at a later point.

Furthermore, the Act provides long lead times so that States and industries have plenty of time to implement new requirements. For example, the proposed standards that we are considering today would not go fully into effect, as part of enforceable implementation plans, for 12 years. That is 12 years after these proposed regulations go into effect that individuals, companies, corporations would feel the full effect of the proposals. If that deadline turns out to be too tight, Congress can extend it, as it has before.

So cost can be taken into account, but only after we have established a standard that protects public health. To my mind, this system has served our country well. That is not to say that establishing a health-based standard is easy. It is not. There are not bright lines. There is no magical level above which everybody gets sick

and below which no one does. Instead, the science of air pollution is extremely complex. Like all science, it is based on hypothesis and experimentation, risk, statistical assumptions, estimates of exposure pathways, and on projections from animal studies to humans. It is never absolutely certain.

But we cannot allow the absence of absolute scientific certainty to paralyze us. As the saying goes, we can't let perfection become the enemy of the good.

Howard Baker put it well in 1969, when he served in the position that Senator Graham now serves in, as the ranking member of the Air Pollution Subcommittee. Talking about an earlier version of the air standards program, Senator Baker said, "There are those who will challenge any criteria which lack final and absolute proof of a direct and causal relationship. But responsible public policy cannot wait upon a perfect knowledge of the cause and effect."

If we cannot achieve perfect knowledge, what should we do? How should we decide, in the fact of uncertainty, whether a new air quality standard is appropriate? In the end, we have to step back, put the slogans and politics behind us, and size it up. The question is not whether the science is perfect. The question is whether, on balance, in the judgment of the mainstream scientific community, the standard will accomplish what the law requires, to protect public health with an adequate margin of safety.

If not, the proposed standards should be modified. If so, then we should work together to see that the proposed standards are implemented reasonably and effectively.

Mr. Chairman, I commend you for calling this hearing and hope that each of us will keep an open mind. This is especially important now that EPA has requested 60 more days to consider public comments. Some groups may be tempted to use that time to build their political case, but that would be a disservice. Let's take this time to listen to the physicians, toxicologists, and epidemiologists, but not to the spin doctors.

Thank you very much. I particularly thank the committee and you, Mr. Chairman, for your indulgence in going over the 5 minutes.

Senator INHOFE. Thank you, Senator Baucus.

I would ask the members of the committee to try to confine their remarks to 5 minutes so that we can get to the witnesses and get our hearing carried on in a timely fashion.

I will follow the "early bird" rule, as has been the custom of this committee, and go now to the first early bird who arrived, Senator Sessions.

**OPENING STATEMENT OF HON. JEFF SESSIONS, U.S. SENATOR
FROM THE STATE OF ALABAMA**

Senator SESSIONS. Thank you, Mr. Chairman. I am glad to be with you today and appreciate you holding hearings today to discuss the science behind the Environmental Protection Agency's proposed changes to ozone and particulate matter standards. I realize this is an extremely technical issue and I am eager to hear testimony from the leading-edge persons in the field.

Like so many of my colleagues, I am concerned about air quality in our country and in my home State of Alabama. I commend the

Environmental Protection Agency for doing a fine job in helping to identify the most polluted areas of our country and those industry and State officials who have made the adjustments—sometimes at great cost—to improve the air we breathe. While there is little dispute in some areas that more improvement is needed, current efforts have resulted in a much higher overall air quality throughout the Nation.

I understand that today's hearing is focused on science because it is only with sound scientific knowledge that we can make good decisions. Changing the ozone and particulate matter standards is by no means a small proposition. The ramifications of enacting new, tighter standards will result in tremendous cost economically and socially. Many industries would be forced to make costly overhauls of their plants and equipment, which could lead to job losses. Likewise, State governments would be forced to shift scarce resources to pollution control.

In short, I want to ensure that the decision to change the ozone and particulate matter are based on sound, definitive scientific data. History has demonstrated that theory, even when supported by some scientific data, cannot be the only basis for action. In 1968, Paul Ehrlich, the renowned doctor of population studies at Stanford University, wrote a book called "The Population Bomb," in which he stated, "The battle to feed all humanity is over. In the 1970's and 1980's, hundreds of millions of people will starve to death." One could easily imagine the terrible problems we would be having today had that happened. That scientist's predictions—thankfully—were not correct.

Before we act to change ozone and particulate standards, we need to identify the problem, understand the underlying science behind the problem, and ask what the most appropriate steps, if any, are needed to solve the problem. I look forward to working with you in that regard.

Senator INHOFE. Thank you, Senator.

Next to arrive is the gentlelady from California, Senator Boxer.

Senator BOXER. Thank you very much, Mr. Chairman.

I want to add my praise to you for having this early hearing. I am very hopeful that we on this committee will be able to work together to do what prior Senators did before we got here. That is to work together so that we protect the health and safety of the people of our country. That is indeed, in my opinion, a great duty and responsibility, perhaps our greatest. We have an Act, the Clean Air Act, that has done this.

I would ask that my entire statement be placed in the record and I will try, in 2 minutes, to sum up.

Senator INHOFE. Without objection, your prepared statement will appear in the record.

**OPENING STATEMENT OF HON. BARBARA BOXER,
U.S. SENATOR FROM THE STATE OF CALIFORNIA**

Senator BOXER. In my home State, exposure of San Francisco Bay Area residents to dangerous levels of ozone has been reduced by 93 percent since 1970. It is a success story. Last year, the Bay Area became the largest metropolitan area in the country to reach attainment of current Federal ozone standards.

However, my State overall continues to face the most challenging and intractable air pollution problems in the Nation. Our south coast basin has the most polluted air in the country. Although we have seen steady improvement, most parts of southern and central California do not meet the current Federal ozone standard or the particulate matter standard.

Air pollution is a very serious problem. For example, according to EPA the current average concentration of fine particulate matter in southeast Los Angeles may be responsible for up to 3,000 deaths annually, and more than 52,000 incidences of respiratory symptoms, including 1,000 hospital admissions.

Young children constitute the largest group of high risk from exposure to air pollutants. They breathe 50 percent more air by body weight than the average adult. In California alone, there are over 6 million children under the age of 14 and approximately 90 percent of them live in areas that fail to meet State and Federal standards.

How are children being affected? Studies show health effects ranging from 20 to 60 percent loss of lung capacity. Despite this, we hear representatives of industry claim that a 30 percent loss of lung capacity is not really a health effect because it is only temporary. Tell that to a mom whose asthmatic child has to stay home or visit the hospital emergency room on a regular basis. Tell that to a mom whose teenage son suffers from continuous coughing, throat irritation, chest pain, and shortness of breath. And what about the potential of causing permanent damage? We do have studies of lab animals which indicate that long-term exposure to ozone causes permanent damage to lungs.

The Clean Air Act directs the Administrator to set standards at levels that, in the judgment of the Administrator, protect the public health with an adequate margin of safety. This is the law. There is no choice here.

Health, in my opinion, must continue to be the marker upon which standards are based. And those standards must be based on science. Once health-based standards are set, cost should play an important role in implementation and timetables.

A lot of serious questions have been raised, Mr. Chairman, about the EPA's proposal. Industry is questioning the strength of the scientific basis for the proposal. Some think it doesn't go far enough. In our search for answers, I think we need to look very closely at what the EPA's Clean Air Scientific Advisory Committee recommended. I won't go into that now because that is what we are going to hear about from the witnesses today. But frankly, the recommendations themselves are not that complicated. The back-up material is.

We should keep our eyes on the two areas: the ozone level and the particulate matter. We must keep the recommendations in mind.

I look forward to working with you, Mr. Chairman, to answer some of these questions. I am hopeful that we can come to this on a bipartisan agreement that we can move forward.

I would particularly like to welcome Dr. Menzel and Dr. Wyzga, who have come from California to testify before you.

Thank you very much.

[The prepared statement of Senator Boxer follows:]

PREPARED STATEMENT OF HON. BARBARA BOXER, U.S. SENATOR FROM THE
STATE OF CALIFORNIA

Mr. Chairman, I believe that as Senators, we have no greater duty and responsibility than to protect the health and safety of the American people.

The Clean Air Act does that and is one of our most successful environmental laws. It is also often referred to as one of our most complex, comprehensive and far reaching environmental laws.

Enormous progress has been made in the last 25 years to control and reduce air pollution. For example, exposure of San Francisco Bay area residents to dangerous levels of ozone has been reduced by 93 percent since 1970. Last year, the Bay area became the largest metropolitan area in the country to reach attainment of current Federal ozone standard.

However my State of California continues to face the most challenging and intractable air pollution problems in the Nation. Our South Coast Basin has the most polluted air in the country, and while we have seen a steady improvement of air quality, most of Southern and Central California does not yet meet the current Federal ozone standard or the particulate matter standard.

Air pollution is a very serious problem. For example, according to the EPA, the current annual average concentrations of fine particulate matter in Southeast Los Angeles County may be responsible for up to 3,000 deaths annually, and more than 52,000 incidents of respiratory symptoms including 1,000 hospital admissions.

Even if current Federal standards were achieved, the Environmental Protection Agency estimates 300–700 fine particle related deaths and more than 40,000 fine particle related health effects.

Young children constitute the largest group at high risk from exposure to air pollutants. They breath 50 percent more air by body weight than the average adult. In California alone there are over six million children under the age of 14 and approximately ninety percent of them live in areas that fail to meet State and Federal standards.

How are our children being affected? Studies show health effects ranging from 20 to 60 percent losses of lung capacity. Despite this, representatives of industry claim that a thirty percent loss of lung capacity is not really a health effect because it is only a temporary reversible loss in lung function. Tell that to a mother whose asthmatic child has to stay home or visit the hospital emergency room on a regular basis. Tell that to a mother whose teenage son suffers from continuous coughing, throat irritations, chest pain and shortness of breath.

And what about the potential of causing permanent damage? We have studies of laboratory animals which indicate that long term exposure to ozone causes permanent damage to the lungs.

Mr. Chairman, in 1988 California expressed belief in the need for stronger clean air standards when we passed the most stringent ozone and particulate matter State standards in the country.

And let me put this in context—we are committed to continuing to make improvements in air quality in a State that is projected to have double digit growth in population (18 percent) in the next 10 years. By the year 2005, we expect to have 38.2 million people in California—up from 32.2 million. We'll have a lot more cars on our highways.

The Clean Air Act directs the Administrator to set standards at levels that in the judgment of the Administrator protect the public health with an adequate margin of safety. Health must continue to be the marker upon which standards are based. And those standards must be based on science. Once health-based standards are set, costs should play an important role in implementation and timetables.

A lot of serious questions have been raised about the Environmental Protection Agency's proposal. Industry is questioning the strength of the scientific basis for the proposal.

In our search for answers, I think we need to look very closely at what the EPA Clean Air Scientific Advisory Committee recommended.

They reviewed the available science and made a determination that there is an adequate scientific basis for the Administrator to revise the standards. For both ozone and particulates, the committee approved the EPA documents and the recommended specific ranges for new more stringent standards. The committee unanimously supported moving from the current 1-hour ozone standard to an 8-hour standard; and 19 of 21 CASAC members supported moving to a fine particle standard for particulates.

As we hear the criticisms of industry, we must constantly keep their final recommendation in our minds. We must not let the complexity of the debate let us forget them.

Mr. Chairman, I am going to work aggressively to pursue answers to the serious questions that have been raised about the EPA proposal and I look forward to working with you, and the other members of this subcommittee.

Mr. Chairman I would like to welcome Dr. Menzel and Dr. Wyzga who have come from California to testify before this subcommittee today.

Thank you.

Senator INHOFE. Thank you, Senator Boxer.
Senator Lieberman.

**OPENING STATEMENT OF HON. JOSEPH I. LIEBERMAN,
U.S. SENATOR FROM THE STATE OF CONNECTICUT**

Senator LIEBERMAN. Thank you, Mr. Chairman. Congratulations on assuming the chairmanship. I look forward to working with you on these important and difficult questions. I totally support your thrust, as stated at the outset, that this is all about trying to find a basis in science for taking the important actions that we are all called on to take.

I am also going to ask that my statement be included in full in the record and see if I can draw more briefly from it.

Senator INHOFE. Without objection, your prepared statement will appear in the record.

Senator LIEBERMAN. To simply restate that these national ambient air quality standards that we are talking about here have been a cornerstone of the Clean Air Act since 1970 and they are based on a judgment that Congress made—and in a sense renewed in the reauthorization in 1990—which is that the ozone, particulate matter, and other common pollutant levels have to be based on a standard that is adequate to protect public health.

We made a judgment here that the basis of the standard was going to be protection of public health with an adequate margin of safety. In fact, the standards are designed to ensure that sensitive groups—not super-sensitive groups—such as children, the elderly, and people with asthma or emphysema, which amounts in total to almost one-third of the American people, do not suffer adverse health effects as a result of breathing unhealthy air.

The point I want to stress is one that I believe Senator Baucus made, which is that while the health standard is the basis for these air quality standards, they are not applied inflexibly. In fact, the plans that the States adopt are able to include specific consideration of cost in deciding how long it should take to implement the health-based standard. It can also have special allowances for small businesses because of the extra dimension of financial difficulty for small businesses.

Areas are given varying times to reach these national health-based standards, depending on how difficult the task is. I can tell you in my own State, Fairfield County—which has a serious problem—is given under our implementation plan 17 years to come into compliance because of the difficulty in doing so. The bottom line is that this approach has been very successful.

Greg Easterbrook, an author, has written on these matters, and he said, “The Clean Air Act isn’t perfect, but it ranks as one of the

most successful, cost-effective government initiatives of the modern era.”

Again, Congress and EPA have been flexible in implementing this Act. EPA has recognized that some deadlines have been difficult to meet because of air that is brought in from outside the State. On two occasions, Congress has extended the time-frame for compliance. EPA, as is the case now, has constantly worked with advisory committees of industry, environmental groups, and others to develop these cost-effective strategies.

In response to the new proposed standards—which I gather are the first since the late 1970’s in the Carter Administration and in the second case since 1987 during the Reagan Administration. There are some understandable questions being raised about the science, but there also seem to me to be some questions raised about whether these air quality standards should continue to be based on health concerns.

Mr. Chairman, I want to say very clearly and strongly that the basic structure of this system, which is health-based air quality standards with cost coming into consideration and a very flexible implementation phase, is resoundingly the right way to go. For me, in one sense, my conclusion is based on a simple proposition which is that people have a right to know, by the best available scientific standards, whether they are breathing clean air.

In areas that don’t meet the standards, people know they are breathing air that presents a risk of their personal health. We can at least explain to them why they are not yet breathing fully clean air, which is that the cost of controls are too expensive, or in some areas it is just impossible to achieve the level we want in an early amount of time.

I am extremely reluctant to change that basic paradigm, which I fear some are asking us to do in response to the proposed standards for ozone and particulate matter. In other words, Mr. Chairman, it is one thing to tell the public, “You won’t have clean air for 10 or 15 or 17 years.” It is quite another to tell the public that they can no longer know whether the air they breathe is clean or dirty because the air quality standards reflect somebody’s mixture of cost feasibility and health consideration.

In terms of setting health-based standards, EPA is inevitably faced with scientific uncertainties. Over the last 25 years, the bipartisan policy has been to err on the side of caution. Understandably so, when one considers the consequences here. But that doesn’t mean they are erring on the side of caution, that is, acting solely on speculation. It means selecting a scientific standard along a continuum of levels that would provide varying degrees of public health protection and then articulating a rationale from a public health perspective for selecting a particular standard.

Let me say finally, Mr. Chairman, that I am impressed that Administrator Browner has relied on a large number of studies conducted by different investigators in various locations in the United States and worldwide, each possessing distinct climates, demographics, and lifestyles. But the conclusions are riveting. EPA concludes that 40,000 people are dying prematurely every year from exposure to particulate matters, even in areas currently meeting the national ambient air quality standard. That is to say that

40,000 people would have lived longer were it not for particulate air pollution.

With respect to ozone, EPA concludes that the new standards are necessary, particularly to protect approximately 13 million kids and 3 million asthmatics.

Finally, for me the statements by the Administrator in her proposed rule present very strong reasons to listen very carefully to her arguments for setting new standards. I am impressed by what she has to say, but these are big decisions with enormous consequences in health and in cost. Therefore, we have to be open to comments from a broad range of people.

That is why I appreciate, Mr. Chairman, the range of witnesses you have called today and why I look forward to the testimony.

[The prepared statement of Senator Lieberman follows:]

PREPARED STATEMENT OF HON. JOSEPH I. LIEBERMAN, U.S. SENATOR FROM THE
STATE OF CONNECTICUT

Thank you, Mr. Chairman. I welcome these hearings and look forward to working with you in your new position as subcommittee chair.

The National Ambient Air Quality Standards have been a cornerstone of the Clean Air Act since 1970. The law requires EPA to set standards to reduce ozone, particulate matter and other common air pollutants at levels which are adequate to protect public health with an adequate margin of safety. The standards are designed to ensure that sensitive groups such as children, the elderly, and people with asthma or emphysema—nearly one third of our population—do not suffer adverse health effects as a result of breathing unhealthy air.

After these standards are set, States must develop implementation plans to meet them. These plans include specific requirements for industry that take cost into account. They can also consider the needs of small businesses. Areas are given varying times to reach the national standards, depending upon how difficult the task. The Fairfield County area of Connecticut, for example, is given 17 years to come into compliance.

This approach has been very successful. Levels of carbon monoxide, lead, volatile organic compounds, particulate matter and sulfur dioxide have dropped dramatically in the period between 1970 and 1995. As Greg Easterbrook has written: "The Clean Air Act isn't perfect, but it ranks as one of the most successful, cost-effective government initiatives of the modern era."

And both Congress and EPA have been flexible in the implementation of the Act. EPA has recognized that certain deadlines are difficult to meet because of transported air pollution. On two occasions, Congress has extended the timeframe for compliance.

Currently, EPA is working with an advisory committee of industry, environmental groups and other interested parties to develop cost-effective strategies for implementing the proposed standards. I'm confident that many very creative ideas will come out of that process and I look forward to its recommendations. That's the history of the Clean Air Act—the development of new technologies and innovative approaches which greatly reduce the cost of compliance.

Questions are now being raised about whether or not air quality standards should be based solely on health concerns. Mr. Chairman, I want to take some time this morning to explain why I strongly believe that the fundamental structure of the Clean Air Act—health-based air quality standards with costs coming into consideration in the implementation phase—is the right one.

In one sense, the answer is simple. People have the right to know whether they are breathing clean air. Today, in areas that don't meet the standards for ozone or particulate matter or carbon monoxide, people *know* they are breathing air that presents a risk for public health. We can also explain to them why they are not yet breathing clean air: costs of controls can be expensive and some areas need time to reach the goals.

I don't want to change that paradigm. If the standards are not based solely on public health, some places in our country could be meeting the standards and still have unhealthy air. What kind of confidence could the public have about such a system? Not very much.

In other words, Mr. Chairman, it's one thing to tell the public that you won't have clean air for 10, 15, or even 17 years because that timeframe will allow for imple-

mentation of more cost effective solutions. It's quite another to tell the public that they can no longer know whether the air they breathe is clean or dirty because the air quality standard reflects some mixture of cost and health considerations. If an area meets an air quality standard, it should mean that the air is clean and healthy to breathe. Anything less is uninformative at best, deceptive at worst.

In terms of setting health based standards, EPA is inevitably faced with scientific uncertainties. Over the last 25 years, the policy has been to err on the side of caution. We must act without scientific certitude because our goal, wherever possible, is a serious one: to prevent deaths and illnesses. Erring on the side of caution does not, of course, mean acting based on speculation. It means selecting a standard along a continuum of levels that would provide varying degrees of public health protection, and articulating a rationale from a public health perspective for selecting one standard and not a lower or higher standard.

Let me comment briefly on the proposals before us. For both of these proposed standards, EPA relied on a large number of studies conducted by different investigators, in various locations in the U.S. and worldwide, each possessing distinct climates, demographics and lifestyles.

With respect to particulate matter, EPA concludes that forty thousand people are dying prematurely every year from exposure to particulate matter even in areas currently meeting the standard—which is to say they would have lived longer were it not for particulate air pollution. Such exposure, according to EPA, also leads to tens of thousands of cases of chronic bronchitis, and hundreds of thousands of incidences of aggravation of asthma and other respiratory symptoms.

With respect to ozone, EPA concludes that new standards are necessary particularly to protect approximately 13 million children and three million asthmatics who are not protected by the current standard from aggravated respiratory problems that can lead to increased hospitalization, illness, days missed from school and work, and other restrictions on activity.

The statements made by Administrator Browner in her proposed rules present compelling reasons to listen carefully to the arguments for setting new standards for ozone and particulate matter. But these are big decisions, and therefore we must be open to comments from a broad a range of people as possible. That's why today's hearing is especially timely and useful.

Mr. Chairman, I come from a State where the air quality is among the worst in the nation—in significant part as a result of air transported from other regions of the country. I have visited St. Francis Hospital in Hartford where people are sick because of air pollution. And it's not unusual for me to receive a letter similar to the one I received in November from a constituent who lives in Fairfield, Connecticut. She told me that her sister has pulmonary disease and every bit of polluted air is harmful to her health. My constituent has no power on her own to protect her sister from pollution. But she has the power, under the Constitution, to petition us and request that we do what we can to clean up the air and protect public health.

That is a proper role of government. Government exists to protect our security. That means defending against threats from abroad. It means protecting us from criminals here at home. And it also means acting to protect the public from pollution that threatens their health, because fighting pollution is a task no individual can accomplish without the help of strong laws and adequate enforcement of those laws.

We may never have air that is completely free of contamination. And we will never have enough money to do everything we should to clean up the air. The question of cost has to come into play in deciding exactly how, and how fast, to reach the goal of cleaner, healthier air. But we should not let cost compromise that goal, lest we lose sight of who we really represent.

Senator INHOFE. Thank you, Senator Lieberman.

The next Senator is Senator Hutchinson, one of our new members.

**OPENING STATEMENT OF HON. TIM HUTCHINSON,
U.S. SENATOR FROM THE STATE OF ARKANSAS**

Senator HUTCHINSON. Thank you, Mr. Chairman.

I want to add my appreciation to you for calling the hearing today. Certainly, as Senator Lieberman said, this is a big decision and it does have enormous consequences. It is a huge issue in the State of Arkansas. I have heard from many of my constituents

about this. I appreciate you calling the hearing to discuss the scientific basis behind the EPA's proposal to further regulate particulates and ozone.

I am not a scientist, and this is one of the most complicated issues with which I have ever dealt. So this hearing is particularly important to my understanding as well as the understanding of my colleagues, as I suspect, as well.

While I do not claim to understand all the intricacies of the scientific research, which has been made available to me, I have learned a great deal and I hope that some of the issues will be explained in more detail today before I make any judgments on the science and the regulations which are proposed. I want to reiterate that I am withholding judgment until I more fully understand the science and perhaps understand the reasoning EPA used to determine their proposal.

One concern I have is the fact that there is no scientific evidence that supports a threshold level for regulation of ozone. We do not know at what point ozone is at a safe level. In addition, as I understand it, there are natural phenomena, which could raise ozone levels above even the current levels for attainment, and well above the proposed standards. If this is the case, it seems possible that certain areas of the country could never be in compliance with the Clean Air Act. Considering the sanctions that EPA has at its disposal, that is a rather daunting possibility.

Perhaps my greatest concern, however, is the lack of data that exists on $PM_{2.5}$. EPA is recommending that particulate matter be regulated at a level that we have not even measured. As I understand the science, there are not enough monitors in the United States that measure $PM_{2.5}$ to justify setting such a stringent standard. Not only can we not measure it, but there is no evidence what types of $PM_{2.5}$ may be the culprit for health problems. My concern is that we could conceivably regulate particulates that are not even the real problem.

As I mentioned, I have not yet decided on a position on the regulations and I feel very strongly that these questions need to be adequately answered before I can make the right decision.

Mr. Chairman, thank you again for having this hearing. I think it shows great insight on your part to convene a hearing on the science issues early on so that we can completely understand these proposed regulations. I thank you for calling the hearing.

[The prepared statement of Senator Hutchinson follows:]

PREPARED STATEMENT OF HON. TIM HUTCHINSON, U.S. SENATOR FROM THE
STATE OF ARKANSAS

Thank you, Mr. Chairman. I sincerely appreciate the opportunity to be here today to discuss the scientific basis behind the EPA's recent proposal to further regulate particulates and ozone. I am not a scientist and this is one of the most complicated issues with which I have ever dealt, so this hearing is particularly important to my understanding, as well as the understanding of my colleagues, I imagine.

I am pleased that we have the opportunity to hear from Dr. George Wolff and Dr. Morton Lippmann, the current and former chairmen of the Clean Air Scientific Advisory Committee, respectively. I trust that your expertise in the issues and your knowledge of the process will prove extremely beneficial to all the members of the committee, as well as the citizens of the United States, as we all try to understand the complicated issues we are about to discuss.

While I do not claim to understand all the intricacies of the scientific research, which has been made available to me, I have learned a great deal and I hope to

have some issues explained in detail, before I make any judgments on the science and the regulations which are proposed. I want to reiterate that I am withholding judgment until I more fully understand the science and perhaps understand the reasoning EPA used to determine their proposal.

One concern I have is the fact that there is no scientific evidence that supports a threshold level for regulation of ozone. We do not know at what point ozone is at a safe level. In addition, as I understand it, there are natural phenomena, which could raise ozone levels above even the current levels for attainment, and well above the proposed standards. If this is the case, it seems possible that certain areas of the country could never be in compliance with the Clean Air Act. Considering the sanctions EPA has at its disposal, this seems to be a daunting possibility.

Perhaps my greatest concern, however, is the lack of data that exists on PM_{2.5}. EPA is recommending that particulate matter be regulated at a level that we have not even measured. As I understand the science, there are not enough monitors in the United States that measure PM_{2.5} to justify setting such a stringent standard. Not only can we not measure it, but there is no evidence what types of PM_{2.5} may be the culprit for health problems. My fear is that we could conceivably regulate particulates that are not even the real problem.

As I mentioned, I have not yet decided on a position on the regulations and I feel very strongly that these questions need to be adequately answered before I can make a decision. Mr. Chairman, thank you for having this hearing. I think it shows great insight on your part to convene a hearing on the science issues early on, so we can completely understand these proposed regulations.

Senator INHOFE. Thank you, Senator Hutchinson.
We will now hear from Senator Allard.

**OPENING STATEMENT OF HON. WAYNE ALLARD, U.S. SENATOR
FROM THE STATE OF COLORADO**

Senator ALLARD. Thank you, Mr. Chairman.

I, too, would like to extend my congratulations to you, the chairman of this subcommittee. I look forward to working with you and the other committee members. I appreciate today's hearing and hope that we can clear the air, so to speak, on at least the science aspect of these regulations so that we can address policy with Administrator Browner next week.

I think today's hearing will be the most important hearing on this issue because it focuses on the science. I hope today we can walk away from this hearing having cleared up the factual dispute over the science of these regulations. If this occurs, then we can either enter into a policy discussion with Administrator Browner next week, or we can decide to get out of the way and allow the EPA to do their work.

However, if today's hearing does not clear up whether the science is sufficient, next week we will have the opportunity to follow up today's discussion with Carol Browner. In any event, I look forward to listening and learning from all our present and future witnesses because learning is what this process is all about.

Over the past several weeks, I have contacted local elected officials in Colorado and also outside scientists. They have certainly helped me understand the importance of this issue to Colorado and the Nation. I might point out that in Colorado we have a special circumstance because of our high altitude. As many other States have special geographic considerations, our altitude does create some special interest, as far as I'm concerned, as to whether it is easier for us to comply or whether it is more difficult.

Mr. Chairman, once again, thank you for calling these hearings.
Senator INHOFE. Thank you, Senator Allard.

We are very pleased today that we have the entire committee present. We will now hear from Senator Graham.

**OPENING STATEMENT OF HON. BOB GRAHAM, U.S. SENATOR
FROM THE STATE OF FLORIDA**

Senator GRAHAM. Mr. Chairman, I do not have an opening statement other than to say that I appreciate the fact that we are holding this hearing so promptly. Today we will focus on the science of the issue and then next week on some of the public policy implications. I believe that is the right sequence in which we should proceed. I look forward to receiving the testimony of this distinguished group this morning.

Senator INHOFE. Thank you, Senator Graham.

For the information of those here today, Senator Graham is the ranking member of this subcommittee.

I am placing in the record at this point the statement of Senator Thomas, a member of the full committee.

[The prepared statement of Senator Thomas follows:]

PREPARED STATEMENT OF HON. CRAIG THOMAS, U.S. SENATOR FROM THE
STATE OF WYOMING

Thank you, Mr. Chairman, for holding this hearing today to discuss the Environmental Protection Agency's (EPA) proposed rule on Particulate Matter (PM) and Ozone. Since the EPA released their criteria on November 27, 1996, State and local governments, grass roots organizations, small businesses—in addition to many of the nation's Governors—have outlined problems and, opposition, to the new regulations. Their concerns need to be heard and fully examined before any final action occurs on this contentious issue. Furthermore, we need to ensure that we are using the best science possible.

At the outset, I want to compliment the EPA for requesting an extension of the comment period an additional 60 days. To quote Senator Chafee in his letter to Molly Clark of the American Lung Association, "this is the largest single regulatory proposal ever made by EPA." With that in mind, and with virtually every industry in America affected by these new standards, it is imperative that additional time be allowed to properly address the impacts these requirements will place on the public.

As we all know, the Clean Air Act (CAA) requires the EPA to identify and set standards for pollutants which potentially threaten public health. Particulate matter and ozone are two of six pollutants for which the EPA has developed National Ambient Air Quality Standards (NAAQS). Currently, we have a PM₁₀ standard which regulates particles 10 microns in diameter and smaller and an allowable level of .12 parts per million cubic feet of ozone. It's important to note that according to the EPA's own reports, these pollutants have been significantly reduced over the past 10 years and will continue to decline as the 1990 Clean Air Act amendments are implemented.

However, the EPA now wants to regulate particulates of 2.5 microns and smaller and initiate a standard of .08 parts per million for ozone. I am skeptical that lowering the NAAQS for particulate matter and ozone will actually achieve the level of protections stated by the EPA. The panelists we will hear from today are experts in the fields of science, health and medicine. I look forward to their testimony and views to see if in fact the EPA's proposed rule is necessary to protect public health.

Mr. Chairman, one of the most troubling aspects of this process is EPA's rush to judgment to implement their proposed PM and ozone regulations before we truly know which particulates cause damaging health effects. I want to make sure that principles of sound science are being applied. As you know, this is a very technical issue and we should be confident that the choices we are making will get to the heart of protecting public health. Unfortunately, I do not believe that has been established. In fact, the EPA's own Clean Air Scientific Advisory Committee (CASAC) stated that "our understanding of the health effects of particulates is far from complete."

I am also concerned about the geographic areas that will be thrown into non-attainment as a result of these standards. The EPA projects that 336 counties nationwide will be in nonattainment as a result of the new ozone rule and 170 coun-

ties will be in nonattainment due to the proposed PM_{2.5} revision. It's no secret that many parts of the country are having problems meeting current emissions reductions. If these requirements are implemented they could actually postpone efforts to achieve attainment status.

Mr. Chairman, we all want to protect public health and the environment. In fact, it was the Bush Administration that passed the Clean Air Act amendments of 1990 and a Republican Congress that passed the Safe Drinking Water Act, the most environmentally friendly farm bill in history and legislation to strengthen food safety laws—all last year.

However, the jury is still out on whether there is sufficient data at this time to decide what changes should be made to the PM and ozone standards. Nonetheless, it is important to have the best scientific data available to us. I compliment the chairman for holding this hearing and look forward to hearing from the witnesses that have been invited to testify before us today. Thank you.

Senator INHOFE. I now ask our first panel of witnesses, Drs. Lippmann and Wolff, to be seated at the witness table.

The way we have divided the panelists today is to start with two members of CASAC, the Clean Air Scientific Advisory Committee. The second panel will be expert scientists in the issue of ozone. The third and final panel will consist of experts who will focus on the particulate matter issue.

While they are coming forward and taking their chairs, I would like to give you an overview of how we will proceed during this public hearing. We have a total of eight witnesses who will be testifying today.

While you listen to testimony that will be given here today, you will hear speakers with whom you agree and disagree. I would like to ask that those of you who are in the audience would not show signs of approval or disapproval. That would be nothing but disruptive to our process.

Each witness will be allocated 5 minutes to give his or her opening statement. There will be lights in front of you, green, yellow, and red. When you see the yellow light, I would ask you to try to conclude your remarks. Of course, when the red light comes on, your time has expired.

Following each of the 5-minute comments by each of the witnesses on the panel, I would then ask any member of the subcommittee if he or she would like to ask questions. Then we will have a round of questions and answers.

I think we are ready to begin. Let me introduce the members of the first panel.

We have Dr. George Wolff, the chairman of the Environment Protection Agency's Clean Air Scientific Advisory Committee, and Dr. Morton Lippmann, professor of environmental medicine, Institute of Environmental Medicine, New York University.

We will begin with Dr. Wolff.

STATEMENT OF GEORGE WOLFF, CHAIRMAN, CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE, GENERAL MOTORS COMPANY

Dr. WOLFF. Thank you, Mr. Chairman, and good morning.

I am George Wolff, principal scientist for General Motors corporate affairs staff. I am here today in my capacity as chairman of EPA's Clean Air Scientific Advisory Committee's panels that reviewed the scientific basis for EPA's proposed changes to the ozone and PM₁₀ standards.

Mr. Chairman, the debate over EPA's recent proposal to revise the standard for ozone and establish a new standard for PM_{2.5}, which is particulate matter with a diameter less than or equal to 2.5 microns, has complex scientific elements. The range of opinions on the reliability of the science varies widely.

CASAC has spent 2 years reviewing the data and studies that form the basis of EPA's proposed rules. I have provided for the record a detailed analysis of the CASAC review process, which I hope will be instructive to the subcommittee in its deliberations.

This morning, I would simply summarize the highlights of the panel's findings on both pollutants.

With respect to ozone, the bottom line is that although the ranges of concentrations and allowable exceedances proposed by EPA were considerable, there was really no bright line which distinguished any of the proposed standards—either the level or the number of allowable exceedances—as being more protective of public health, including the present standard. The weight of evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations.

Based on information now available, it appears that some individuals may respond to ozone exposure no matter what the level. What this means is that the old paradigm of identifying the lowest observable effects level and then providing an adequate margin of safety is not possible, either in practice or theory. It further means that as a consequence, EPA risk assessments must play a key role in identifying an appropriate level.

In reaching the conclusion that there is no bright line in terms of public health benefits, we found, for example, that the differences of percent of outdoor children responding between the present standard and EPA's more stringent proposal—that is, 8 hours, one exceedance at .07 parts per million—were statistically insignificant for all health endpoints. Further, when ozone-aggravated asthma admissions were compared to total asthma admissions, the differences between the various options were small.

As a consequence, the panel concluded that the selection of a specific level and number of allowable exceedances is a policy judgment rather than a decision based on the underlying science.

In summary, the scientific community has made great strides in its understanding the health effects of ozone exposure because of ongoing research programs. Nevertheless, there are still many gaps in our knowledge and large uncertainties in many of the risk assessments. The good news is that the scientific community may now be in a position to frame the important questions that need to be addressed before the next ozone review is completed in 5 years.

Turning to PM, our understanding of the health effects of PM is far from complete. Having said that, the panel agreed that retaining the annual PM₁₀ standards at their current level is appropriate at this time. There was also consensus that a new PM_{2.5} standard be established to distinguish between coarse and fine particles.

However, there was no consensus on the level, averaging time, or form of the standard. For example, four panelists supported specific ranges near the lower end of EPA's proposal. Eight others de-

clined to select a specific range at all. Seven selected a level near, at, or above EPA's proposal. Two members recommended against the PM_{2.5} standard.

At least in part, this diversity of opinion can be attributed to the accelerated review schedule. The deadlines did not allow adequate time to analyze, integrate, interpret, or debate the available data on this very complex issue. Nor does the court-ordered deadline recognize that achieving the goal of a scientifically defensible standard may require interim steps.

The diversity of opinion among CASAC members underscores the many unanswered questions and uncertainties associated with establishing causality between PM_{2.5} and premature death. Among these are exposure misclassification, lack of understanding of toxicological mechanisms, and the existence of possible alternative explanations.

The panel expressed its desire to avoid being in a similar situation when the next PM review cycle is undertaken, and therefore urged EPA to implement immediately a targeted research program to address these unanswered questions and uncertainties. The panel also believed that it is essential that EPA obtain long-term PM_{2.5} measurements.

Mr. Chairman, that concludes my formal remarks. I will be happy to respond to any questions the subcommittee may have.

Senator INHOFE. Thank you, Dr. Wolff.

Dr. Lippmann.

STATEMENT OF MORTON LIPPMANN, INSTITUTE OF ENVIRONMENTAL MEDICINE, NEW YORK UNIVERSITY

Dr. LIPPMANN. Thank you, Mr. Chairman.

My full statement gives my background. I have personally been involved in research on this issue for many decades.

Senator INHOFE. Without objection, your prepared statement will appear in the record.

Dr. LIPPMANN. In fact, the size selective standards were based largely on my lab work. I have done the physiology and deposition studies that support that. I also started the chain of studies in the natural setting showing exposure response relationships for ozone to children, where there is no question that higher exposures produce greater responses. Dr. Thurston will later talk about our studies in asthmatic children, which show medication usage is directly related to the ozone and sulfate levels.

In my view, the EPA proposals for the revised standards are clearly not too strict, since they will permit exposure that will cause excess mortality and morbidity. In my view, the EPA Administrator has made a prudent public health judgment in her selections of the standards.

The Administrator's decision to proceed with changes in both at the same time is a good one because both pollutants come from the same sources. They interact and it doesn't make sense economically or otherwise to attack the one pollutant and not the other.

CASAC did fully endorse the ranges proposed by staff and the Administrator has made her selections within those ranges. For ozone the current standard of 120 parts per billion for an hour is equivalent to an 8-hour max of 90, based on the third highest. So

we are essentially only reducing the permissible exposure from 90 to 80. The difference is in changing the average time to 8-hour from 1-hour, which is in relation to the way people respond to ozone. They don't respond immediately. The response builds up over successive hours.

By contrast, the recent air quality guideline exercise by the World Health Organization (WHO) in Europe, just completed, proposes an 8-hour level of 60 parts per billion, considerably more conservative than the EPA proposal.

For PM, the 50 microgram per cubic meter (mg/m^3) annual average would be retained without change. But the 24-hour PM_{10} is being relaxed because it is now being based on multiple exceedances, and not on a single exceedance. That is OK, because we don't really believe the coarse component, which drives the PM_{10} concentration, is having the effects that the fine particles are. If we don't have a standard for fine particles, we don't attack the problem that is causing the particulate-related health effects.

The WHO Europe exercise in air quality guidelines for particulate matter say that they can't even establish a traditional guideline because there is excess mortality at every level. Therefore, they say that the national authorities which use these guidelines have to decide how much they can tolerate. Less is better, that is, more protective. More means more people are affected. CASAC endorsed a range. The EPA Administrator has selected something toward the upper side of the range on a 24-hour basis.

She certainly is being prudent. She is heightening the standard somewhat, but not going down to what the lowest-effects level is. The lowest level that is appropriate is uncertain because we don't know the compositional factors. The next time we do this, the standard should ideally be directed at the specific toxic components within the particle mixture. But the evidence is absolutely clear that it is the fine particles which are most closely related to the mortality and the morbidity, and lowering the limits for fine particles a bit is a prudent public health judgment.

I won't go into all the things particles do. Senator Lieberman mentioned it, Senator Baucus mentioned it. But to save time, I would like to point out that it is misleading to talk about the number of communities going out of compliance. Many communities, which would be just below the current standards, may turn out to be just above the new standards. However, the particulate trends are going down. We will have a long timeframe for implementation of the new standards. By the time the standards are implemented, there won't be that many communities who will have to take drastic action. We are talking about an incremental reduction in protection, which is prudent public policy.

So CASAC endorsed the ranges proposed by EPA staff. The Administrator certainly didn't go to the lower end of the range. What we must recognize is that there are major unknowns left, and that we will be in the same box 5 years from now unless the Agency has more resources to find out what we don't know now. Dr. Wolff and I certainly agree entirely—as does everyone else in science on this issue—that we need more money to find out what the problem is and how we can do a better job when the standard cycle comes around again.

My personal estimate is that we should be spending at least \$50 million a year, which is small change when compared to the health effects benefit, and even to the control costs. Right now, we are a bit in the dark, but a judgment call is called for by the Administrator because the Act says that she must look at these standards periodically. I think she has made a prudent judgment call and that we need to get on with it. We need to address the unknown and come back to this again in 5 years.

Senator INHOFE. Thank you, Dr. Lippmann.

You say that you need more money. We haven't heard that before.

[Laughter.]

Senator INHOFE. Dr. Wolff, perhaps you could help me better understand the type of science that is being used in these studies, particularly the PM studies which apparently were epidemiological studies.

Do epidemiological studies basically examine the statistical relationship between health effects or diseases with different possible factors versus other studies, such as toxicology and physiology, which deal with biological mechanisms?

Dr. WOLFF. That is correct. The epidemiological studies are based on statistical relationships between two observations.

Senator INHOFE. So basically statistics versus biological mechanisms?

Dr. WOLFF. The toxicological studies are looking for biological mechanisms.

Senator INHOFE. I understand that there is not a biological mechanism for PM. Is that true?

Dr. WOLFF. This was a contention of several members that were on the CASAC. Most notably, Dr. Mark Utell, who is a chest physician, kept reminding us that there was no plausible biological mechanism that he could use to explain the statistical relationship.

Senator INHOFE. Those of us—and of course, I guess I speak for everyone on this panel who are non-scientists, and laymen, so to speak—it is very difficult to understand the risk factors shown in these studies. I read an article that was given to me by staff in this Science Magazine called “Epidemiology Faces Its Limits”.

Without objection, I would like to enter this article in the record. [The referenced article follows:]

[From Science, July 14, 1995]

EPIDEMIOLOGY FACES ITS LIMITS

(By Gary Taubes)

The news about health risks comes thick and fast these days, and it seems almost constitutionally contradictory. In January of last year, for instance, a Swedish study found a significant association between residential radon exposure and lung cancer. A Canadian study did not. Three months later, it was pesticide residues. The Journal of the National Cancer Institute published a study in April reporting—contrary to previous, less powerful studies—that the presence of DDT metabolites in the bloodstream seemed to have no effect on the risk of breast cancer. In October, it was abortions and breast cancer. Maybe yes. Maybe no. In January of this year it was electromagnetic fields (EMF) from power lines. This time a study of electric utility workers in the United States suggested a possible link between EMF and brain cancer but—contrary to a study a year ago in Canada and France—no link between EMF and leukemia.

These are not isolated examples of the conflicting nature of epidemiologic studies; they're just the latest to hit the newspapers. Over the years, such studies have come up with a mind-numbing array of potential disease-causing agents, from hair dyes (lymphomas, myelomas, and leukemia) to coffee (pancreatic cancer and heart disease) to oral contraceptives and other hormone treatments (virtually every disorder known to woman). The pendulum swings back and forth, subjecting the public to an "epidemic of anxiety," as Lewis Thomas put it over a decade ago. Indeed, last July, the *New England Journal of Medicine* (NEJM) published an editorial by editors Marcia Angell and Jerome Kassirer asking the pithy question, "What Should the Public Believe?" Health-conscious Americans, wrote Angell and Kassirer, "increasingly find themselves beset by contradictory advice. No sooner do they learn the results of one research study than they hear of one with the opposite message."

Kassirer and Angell place responsibility on the press for its reporting of epidemiology, and even on the public "for its unrealistic expectations" of what modern medical research can do for their health. But many epidemiologists interviewed by *Science* say the problem also lies with the very nature of epidemiologic studies—in particular those that try to isolate causes of noninfectious disease, known variously as "observational" or "risk-factor" or "environmental" epidemiology.

The predicament of these studies is a simple one: Over the past 50 years, epidemiologists have succeeded in identifying the more conspicuous determinants of noninfectious diseases—smoking, for instance, which can increase the risk of developing lung cancer by as much as 3000 percent. Now they are left to search for subtler links between diseases and environmental causes or lifestyles. And that leads to the Catch-22 of modern epidemiology.

On the one hand, these subtle risks—say, the 30 percent increase in the risk of breast cancer from alcohol consumption that some studies suggest—may affect such a large segment of the population that they have potentially huge impacts on public health. On the other, many epidemiologists concede that their studies are so plagued with biases, uncertainties, and methodological weaknesses that they may be inherently incapable of accurately discerning such weak associations. As Michael Thun, the director of analytic epidemiology for the American Cancer Society, puts it, "With epidemiology you can tell a little thing from a big thing. What's very hard to do is to tell a little thing from nothing at all." Agrees Ken Rothman, editor of the journal *Epidemiology*: "We're pushing the edge of what can be done with epidemiology."

With epidemiology stretched to its limits or beyond, says Dimitrios Trichopoulos, head of the epidemiology department at the Harvard School of Public Health, studies will inevitably generate false positive and false negative results "with disturbing frequency." Most epidemiologists are aware of the problem, he adds, "and tend to avoid causal inferences on the basis of isolated studies or even groups of studies in the absence of compelling biomedical evidence. However, exceptions do occur, and their frequency appears to be increasing." As Trichopoulos explains, "Objectively the problems are not more than they used to be, but the pressure is greater on the profession, and the number who practice it is greater."

As a result, journals today are full of studies suggesting that a little risk is not nothing at all. The findings are often touted in press releases by the journals that publish them or by the researchers' institutions, and newspapers and other media often report the claims uncritically (see box on p. 166). And so the anxiety pendulum swings at an ever more dizzying rate. "We are fast becoming a nuisance to society," says Trichopoulos. "People don't take us seriously anymore, and when they do take us seriously, we may unintentionally do more harm than good." As a solution, epidemiologists interviewed by *Science* could suggest only that the press become more skeptical of epidemiologic findings, that epidemiologists become more skeptical about their own findings—or both.

AN OBSERVATIONAL SCIENCE

What drives the epidemiologic quest for risk factors is the strong circumstantial evidence that what we eat, drink, breathe, and so on are major factors in many devastating illnesses. Rates of heart disease, for example, have changed much faster over recent decades than can be explained by genetic changes, implicating dietary and environmental causes. And the fact that no single cancer affects every population at the same rate suggests that factors external to the human body cause 70 percent to 90 percent of all cancers. In other words, says Richard Peto, an Oxford University epidemiologist, "there are ways in which human beings can live whereby those cancers would not arise." Only a few of these environmental factors are known—cigarette smoke for lung cancer, for example, or sunlight for skin cancer—and epidemiology seems to provide the best shot at identifying the others.

The most powerful tool for doing so is the randomized trial, which is the standard for studies of new drugs and other medical research: Assign subjects at random to test and control groups, alter the exposure of the test group to the suspected risk factor, and follow both groups to learn the outcome. Often, both the experimenters and the subjects are “blinded”—unaware who is in the test group and who is a control. But randomized trials would be prohibitively slow and expensive for most risk factors, because they can take years or decades to show an effect and hundreds of thousands of individuals may need to be followed to detect enough cases of the disease for the results to be significant. And randomly subjecting thousands of healthy people to pollutants or other possible carcinogens raises obvious ethical problems.

Because the experimental approach is off limits for much of epidemiology, researchers resort to observational approaches. In case-control studies, for example, they select a group of individuals afflicted with a particular disorder, then identify a control group free of the disorder and compare the two, looking for differences in lifestyle, diet, or some environmental factor. Potentially more reliable, but also much more costly, are cohort studies, in which researchers take a large population—as many as 100,000—and question the subjects in detail about their habits and environment. They then follow the entire population for years or decades to see who gets sick and who doesn’t, what diseases they suffer from, and what factors might be different between them. Either way, risk-factor epidemiology is “a much duller scalpel” than randomized trials, says Scott Zeger, a biostatistician at the Johns Hopkins School of Mental and Public Health.

What blunts its edge are systematic errors, known in the lingo as biases and confounding factors. “Bias and confounders are the plague upon the house of epidemiology,” says Philip Cole, chair of epidemiology at the University of Alabama. They represent anything that might lead an epidemiologic study to come up with the wrong answer, to postulate the existence of a causal association that does not exist or vice versa.

Confounding factors are the hidden variables in the populations being studied, which can easily generate an association that may be real but is not what the epidemiologist thinks it is. A ubiquitous example is cigarette smoking, which can confound any study looking, for instance, at the effects of alcohol on cancer. “It just so happens,” explains Trichopoulos, “that people who drink also tend to smoke,” boosting their risk of cancer. As a result, epidemiologists face the possibility that any apparent cancer-alcohol link may be spurious. Smoking may also have confounded a study Trichopoulos himself co-authored linking coffee-drinking and pancreatic cancer—a finding that has not been replicated. The study, published over a decade ago, corrected for smoking, which often accompanies heavy coffee drinking—but only for smoking during the 5 years before the cancer was diagnosed. Trichopoulos now says that he and his colleagues might have done better to ask about smoking habits a full 20 years before diagnosis.

Biases are problems within study designs themselves. The process of choosing an appropriate population of controls in a case-control study, for instance, can easily lead to an apparent difference between cases and controls that has nothing to do with what caused the disease. “It’s often not even theoretically clear who the right comparison group is,” says Harvard epidemiologist Walter Willett. “And sometimes, even if you can design the study so that you have the theoretically correct comparison group, you usually don’t get everybody willing to participate, and the people who do participate in your study will be different from the people who don’t, often in health-related ways.”

For example, Charles Poole of Boston University has spent several years analyzing the results and methodology of a 1988 study of EMF and cancer, which found that exposure to relatively high EMF from power lines appeared to increase the risk of leukemia and brain cancer in children. David Savitz of the University of North Carolina, the study’s author, selected controls for that study with a common technique known as random digit dialing: Researchers take the phone numbers of their cases and randomly change the last four digits until they find a suitable control. Random digit dialing, however, seems to create “a pronounced bias toward the control group being deficient in persons of very low socioeconomic status,” says Poole. Poor people, it seems, are either less likely to be home during the day to answer the phone, less likely to want to take part in a study, or less likely to have an answering machine and call the researchers back.

Indeed, the North Carolina researchers reported that their data showed that the risk of leukemia and brain cancer rises not just with exposure to EMF but also with higher levels of breast-feeding, maternal smoking, and traffic density, all of which are markers for poverty. This suggests, says Poole, that the study group was poorer than the controls, and that some poverty-associated factor other than EMF could have resulted in the apparent increase in cancer risk. Nonetheless, the study is still

cited as supporting the hypothesis that EMF causes childhood cancer, although even Savitz concedes that the random dig-it dialing problem is “a legitimate source of uncertainty.”

Even when such biases can be identified, their magnitude—and sometimes even their direction—can be nearly impossible to assess. David Thomas, for example, an epidemiologist at the Fred Hutchinson Cancer Research Center in Seattle, points to studies analyzing the effect of Breast Self-Examination (BSE) on breast cancer mortality rates, which, he says, have yielded some “modest suggestion that there might be a beneficial effect” from BSE. “You have to ask what motivates a woman to practice BSE,” says Thomas. “Maybe she has a strong family history of breast cancer. If so, she’s more likely to get breast cancer. That would be an obvious bias,” which could make BSE look less useful than it is. “Or maybe a woman with a strong family history of breast cancer would be afraid to practice BSE. You have no way of predicting the direction of the bias. So it would be very difficult to interpret your results. You have to go to a randomized study to get a reliable answer.”

TRICKS OF MEMORY

Of all the biases that plague the epidemiologic study of risk factors, the most pernicious is the difficulty of assessing exposure to a particular risk factor. Rothman, for instance, calls it “a towering obstacle.” When exposure can be measured reliably, a subtle association may be credible—as it is in the case of early childbirth and a lower risk of breast cancer. The reason is that both cause and effect can be measured with some certainty, says Harvard epidemiologist Jamie Robins. “It’s easy to know which people got breast cancer, and it’s easy to know at what age they had kids,” he says, adding that virtually every study on the subject comes to the same conclusion: Early childbirth reduces the risk by about 30 percent.

But epidemiologists are quick to list risk factors for which accurate exposure measurements are virtually impossible. Joe Fraumeni, director of the epidemiology and biostatistics program at the National Cancer Institute (NCI), points to radon: “When you’re studying smoking,” he says, “that’s easy. Just count the number of cigarettes and duration and packs per day. But something like radon, how do you measure exposure, particularly biologically relevant exposure that has taken place in the past?” Equally uncertain are those risk factors recorded only in human memory, such as consumption of coffee or dietary fat. Ross Prentice of the University of Washington notes, for example, that underweight individuals tend to overreport fat intake on questionnaires or in interviews and obese subjects tend to underreport it.

Such recall bias is known to be especially strong, as Willett points out, among patients diagnosed with the disease in question or among their next of kin. In studies of a possible relationship between fat intake and breast cancer, for instance, says Willett, “people may recall their past intake of fat differently if they have just been diagnosed with breast cancer than if you pluck them out of a random sample, call them up out of the blue over the phone, and ask them what their past diet was.”

Recall bias, for instance, apparently accounts for the conflicting findings about oral contraceptive use and breast cancer. Many studies have looked for this association over the years, both case-control studies and cohort studies. Trichopoulos notes that case-control studies have tended to show an association between oral contraceptives and breast cancer, while cohort studies have not. Epidemiologists who have done cohort studies say the problem is in case-control studies, which are thrown off by recall bias—women who are diagnosed with breast cancer are more likely to give complete information about contraceptive use than women who don’t. Those who did case-control studies say the bias is in the cohort studies. Cohort studies have to rely on impersonal questionnaires because they are so much larger than case-control studies, and women are less likely to give complete and honest information than they are in the more intimate interviews possible in case-control studies. “The point,” says Trichopoulos, “is which do we believe.”

It’s not just the subjects of studies who are prone to bias; epidemiologic studies can be plagued by interviewer bias as well. The interviewers are rarely blinded to cases and controls, after all, and questionnaires, the traditional measuring instrument of epidemiology, are neither peer-reviewed nor published with the eventual papers. “In the laboratory,” as Yale University clinical epidemiologist Alvin Feinstein puts it, “you have all kinds of procedures for calibrating equipment and standardizing measurement procedures. In epidemiology ... it’s all immensely prey to both the vicissitudes of human memory and the biases of the interview.”

SALVATION FROM STATISTICS?

With confounders, biases, and measurement errors virtually inevitable, many epidemiologists interviewed by *Science* say that risk-factor epidemiology is increasingly straying beyond the limits of the possible no matter how carefully the studies are done. "I have trouble imagining a system involving a human habit over a prolonged period of time that could give you reliable estimates of risk increases that are of the order of tens of percent," says Harvard epidemiologist Alex Walker. Even the sophisticated statistical techniques that have entered epidemiologic research over the past 20 years—tools for teasing out subtle effects, calculating the theoretical effect of biases, correcting for possible confounders, and so on—can't compensate for the limitations of the data, says biostatistician Norman Breslow of the University of Washington, Seattle.

"In the past 30 years," he says, "the methodology has changed a lot. Today people are doing much more in the way of mathematical modeling of the results of their study, fitting of regression equations, regression analysis. But the question remains: What is the fundamental quality of the data, and to what extent are there biases in the data that cannot be controlled by statistical analysis? One of the dangers of having all these fancy mathematical techniques is people will think they have been able to control for things that are inherently not controllable."

Breslow adds that epidemiologist will commonly report that they have unveiled a possible causal association between a risk factor and a disease because the association is "statistically significant," meaning that the error bars—the limits of a 95 percent confidence interval—do not include the null result, which is the absence of an effect. But, as Breslow explains, such statistical "confidence" means considerably less than it seems to. The calculation of confidence limits only takes into consideration random variation in the data. It ignores the systematic errors, the biases and confounders, that will almost invariably overwhelm the statistical variation.

University of California, Los Angeles (UCLA) epidemiologist Sander Greenland says most of his colleagues fail to understand this simple point. "What people want to do when they see a 95 percent confidence interval," he says, "is say 'I bet there's a 95 percent chance the true value is in there.' Even if they deny it, you see them behaving and discussing their study result as though that's exactly what it means. There are certain conditions under which it's not far from the truth, but those conditions are generally not satisfied in an epidemiologic study."

WHAT TO BELIEVE?

So what does it take to make a study worth taking seriously? Over the years, epidemiologists have offered up a variety of criteria, the most important of which are a very strong association between disease and risk factor and a highly plausible biological mechanism. The epidemiologists interviewed by *Science* say they prefer to see both before believing the latest study, or even the latest group of studies. Many respected epidemiologist, have published erroneous results in the past and say it is so easy to be fooled that it is almost impossible to believe less-than-stunning results.

Sir Richard Doll of Oxford University, who once co-authored a study erroneously suggesting that women who took the anti-hypertension medication reserpine had up to a fourfold increase in their risk of breast cancer, suggests that no single epidemiologic study is persuasive by itself unless the lower limit of its 95 percent confidence level falls above a threefold increased risk. Other researchers, such as Harvard's Trichopoulos, opt for a fourfold risk increase as the lower limit. Trichopoulos's ill-fated paper on coffee consumption and pancreatic cancer had reported a 2.5fold increased risk.

"As a general rule of thumb," says Angell of the *New England Journal*, "we are looking for a relative risk of three or more before accepting a paper for publication!, particularly if it is biologically implausible or if it's a brand-new finding." Robert Temple, director of drug evaluation at the Food and Drug Administration, puts it bluntly: "My basic rule is if the relative risk isn't at least three or four, forget it." But as John Bailar, an epidemiologist at McGill University and former statistical consultant for the *NEJM*, points out, there is no reliable way of identifying the dividing line. "If you see a 10fold relative risk and it's replicated and it's a good study with biological backup, like we have with cigarettes and lung cancer, you can draw a strong inference," he says. "If it's a 1.5 relative risk, and it's only one study and even a very good one, you scratch your chin and say maybe."

Some epidemiologists say that an association with an increased risk of tens of percent might be believed if it shows up consistently in many different studies. That's the rationale for meta-analysis—a technique for combining many ambiguous studies to see whether they tend in the same direction (*Science*, 3 August 1990, p. 476). But when *Science* asked epidemiologists to identify weak associations that are now con-

sidered convincing because they show up repeatedly, opinions were divided—consistently.

Take the question of alcohol and breast cancer. More than 50 studies have been done, and more than 30 have reported that women who drink alcohol have a 50 percent increased risk of breast cancer. Willett, whose Nurse's Health Study was among those that showed a positive association, calls it "highly probable" that alcohol increases the risk of breast cancer. Among other compelling factors, he says, the finding has been "reproduced in many countries with many investigators controlling for lots of confounding variables, and the association keeps coming up." But Greenland isn't so sure. "I'd bet right now there isn't a consensus. I do know just from talking to people that some hold it's a risk factor and others deny it." Another Boston-based epidemiologist, who prefers to remain anonymous, says nobody is convinced of the breast cancer-alcohol connection "except Walt Willett."

Another example is long-term oral contraceptive use and breast cancer, a link that has been studied for a quarter of a century. Thomas of the Fred Hutchinson Cancer Research Center says he did a meta-analysis in 1991 and found a dozen studies showing a believable association in younger women who were long-time users of oral contraceptives. "The bottom line," he says, "is it's taken us over 20 years of studies before some consistency starts to emerge. Now it's fairly clear there's a modest risk." But Noel Weiss of the University of Washington says he did a similar review of the data that left him unconvinced. "We don't know yet," he says. "There is a small increased risk associated with oral contraceptive use, but what that represents is unclear." Mary Charleson, a Cornell Medical Center epidemiologist, calls the association "questionable." Marcia Angell calls it "still controversial."

Consistency has a catch, after all, explains David Sackett of Oxford University: It is persuasive only if the studies use different architectures, methodologies, and subject groups and still come up with the same results. If the studies have the same design and "if there's an inherent bias," he explains, "it wouldn't make any difference how many times it's replicated. Bias times 12 is still bias." What's more, the epidemiologists interviewed by Science point out that an apparently consistent body of published reports showing a positive association between a risk factor and a disease may leave out other, negative findings that never saw the light of day.

"Authors and investigators are worried that there's a bias against negative studies," and that they will not be able to get them published in the better journals, if at all, says Angell of the NEJM. "And so they'll try very hard to convert what is essentially a negative study into a positive study by hanging on to very, very small risks or seizing on one positive aspect of a study that is by and large negative." Or, as one National Institute of Environmental Health Sciences researcher puts it, asking for anonymity, "Investigators who find an effect get support, and investigators who don't find an effect don't get support. When times are tough it becomes extremely difficult for investigators to be objective."

When asked why they so willingly publish inconclusive research, epidemiologists say they have an obligation to make the data public and justify the years of work. They also argue that if the link is real, the public health effect may be so dramatic that it would be irresponsible not to publish it. The University of North Carolina's Savitz, for instance, who recently claimed a possible link between EMF exposure and a tens of percent increase in the risk of breast cancer, says: "This is minute. . . . But you could make an argument that even if this evidence is 1000fold less than for an EMF-leukemia link, it is still more important, because the disease is 1000fold more prevalent."

One of the more pervasive arguments for publishing weak effects, Rothman adds, is that any real effect may be stronger than the reported one. Any mismeasurement of exposure, so the argument goes, will only serve to reduce the observed size of the association. Once researchers learn how to measure exposure correctly, in other words, the actual association will turn out to be bigger—and thus more critical to public health. That was the case in studies of steelworkers and lung cancer decades ago, says Robins. Early studies saw only a weak association, but once researchers homed in on coke-oven workers, the group most exposed to the carcinogens, the relative risk shot up. None of the epidemiologists who spoke to Science could recall any more recent parallels, however.

AN UNHOLY ALLIANCE

There would be few drawbacks to publishing weak, uncertain associations if epidemiologists operated in a vacuum, wrote Brian Mac-Mahon, professor emeritus of epidemiology at Harvard, in an April 1994 editorial in the *Journal of the National Cancer Institute*. But they do not, he said. "And, however cautiously the investigator may report his conclusions and stress the need for further evaluation," he added,

“much of the press will pay little heed to such cautions. . . . By the time the information reaches the public mind, via print or screen, the tentative suggestion is likely to be interpreted as a fact.”

This is what one epidemiologist calls the “unholy alliance” between epidemiology, the journals, and the lay press. The first one or two papers about a suspected association “spring into the general public consciousness in way that does not happen in any other field of scientific endeavor,” says Harvard’s Walker. And once a possible link is in the public eye, it can be virtually impossible to discredit. As far as scientists were concerned, for instance, a 1981 epidemiologic study put to rest a suggestion that saccharine can cause bladder cancer—one of the few cases in which epidemiology had managed to put an end to a suspected association. Yet 14 years later, television advertisements for Nutra-Sweet, which contains the artificial sweetener aspartame, still tout it as the sweetener that does not have saccharine.

Epidemiologists themselves are at a loss as to how to curb the “anxiety of the week” syndrome. Many, like Rothman, simply argue that risk factor epidemiology is a young science that will take time to mature. Others, like Robins, suggest that barring a major breakthrough in the methodological tools of epidemiology, maturity will be hard to come by. The pressures to publish inconclusive results and the eagerness of the press to publicize them, he and others say, mean that the anxiety pendulum, like Foucault’s, will continue to swing indefinitely (see box on p. 165).

The FDA’s Temple does make one positive suggestion: Although risk-factor epidemiology will never be as sharp a tool as randomized clinical trials, epidemiologists could still benefit by adopting some of the scientific practices of those studies. “The great thing about a clinical control trial,” he says, “is that, within limits, you don’t have to believe anybody or trust anybody. The planning for a clinical control trial is prospective; they’ve written the protocol before they’ve done the study, and any deviation that you introduce later is completely visible.” While agencies like the NCI do insist on seeing study protocols in risk-factor epidemiology prospectively, this is still not standard procedure throughout the field. Without it, says Temple, “you always wonder how many ways they cut the data. It’s very hard to be reassured, because there are no rules for doing it.”

In the meantime, UCLA’s Greenland has one piece of advice to offer what he calls his “most sensible, level-headed, estimable colleagues.” Remember, he says, “there is nothing sinful about going out and getting evidence, like asking people how much do you drink and checking breast cancer records. There’s nothing sinful about seeing if that evidence correlates. There’s nothing sinful about checking for confounding variables. The sin comes in believing a causal hypothesis is true because your study came up with a positive result, or believing the opposite because your study was negative.”

* * * * *

SIZING UP THE CANCER RISKS

In the history of epidemiology, only a dozen or so environmental agents have ever been repeatedly and strongly linked to human cancer, says University of Alabama epidemiologist Philip Cole. Among them are cigarette smoke, alcohol, ionizing radiation, a few drugs, a handful of occupational carcinogens, such as asbestos, and perhaps three viruses—hepatitis-B virus, human T cell leukemia virus, and human papillomavirus. But every year, epidemiologic papers are published by the journal load, many of them reporting new potential causes of cancer in the environment.

Most are the product of observational epidemiology, in which researchers try to compare the lives of people suffering from a disease with those of healthy controls. Even its practitioners admit this effort is plagued by biases and confounding factors (see main text). As a result, most epidemiologists interviewed by Science said they would not take seriously a single study reporting a new potential cause of cancer unless it reported that exposure to the agent in question increased a person’s risk by at least a factor of 3—which is to say it carries a risk ratio of 3. Even then, they say, skepticism is in order unless the study was very large and extremely well done and biological data support the hypothesized link. Sander Greenland, a University of California, Los Angeles, epidemiologist, says a study reporting a twofold increased risk might then be worth taking seriously—“but not that seriously.”

Few of the entries in the following list of potential cancer risks, reported in the journals and picked up in the popular press over the past 8 years, have come close to fulfilling those criteria. Are these dangers real? As the saying goes, you be the judge.

High-cholesterol diet—risk ratio (rr) 1.65 for rectal cancer in men (January 1987)
Eating yogurt at least once a month—rr 2 for ovarian cancer (July 1989)

Smoking more than 100 cigarettes in a lifetime—rr 1.2 for breast cancer (February 1990)
 High-fat diet—rr 2 for breast cancer (August 1990)
 Lengthy occupational exposure to dioxin—rr 1.5 for all cancers (January 1991)
 Douching once a week—rr 4 for cervical cancer (March 1991)
 Regular use of high-alcohol mouthwash—rr 1.5 for mouth cancer (June 1991)
 Use of phenoxy herbicides on lawns—rr 1.3 for malignant lymphoma in dogs (September 1991)
 Weighing 3.6 kilograms or more at birth—rr 1.3 for breast cancer (October 1992)
 Vasectomy—rr 1.6 for prostate cancer (February 1993)
 Pesticide exposure, indicated by high residues in blood—rr 4 for breast cancer (April 1993); contradicted 1 year later in a larger study with one of the same authors.
 Drinking more than 3.3 liters of fluid (particularly chlorinated tap water) a day—rr 2—4 for bladder cancer (July 1993)
 Experiencing psychological stress in the workplace—rr 5.5 for colorectal cancer (September 1993)
 Diet high in saturated fat—rr 6 for lung cancer in nonsmoking women (December 1993)
 Eating more than 20 grams of processed meats (i.e., bologna) a day—rr 1.72 for colon cancer (February 1994)
 Eating red meat five or more times a week—rr 2.5 for colon cancer (February 1994)
 Occupational exposure to electromagnetic fields—rr 1.38 for breast cancer (June 1994)
 Smoking two packs of cigarettes a day—rr 1.74 for fatal breast cancer (July 1994)
 Eating red meat twice a day—rr 2 for breast cancer (July 1994)
 Regular cigarette smoking—rr 1.7 for pancreatic cancer (October 1994)
 Ever having used a sun lamp—rr 1.3 for melanoma (November 1994)
 Abortion—rr 1.5 for breast cancer (November 1994)
 Having shorter or longer than average menstrual cycles—rr 2 for breast cancer (December 1994)
 Obesity in men (the heaviest 25 percent of those in the study)—rr 3 for esophageal cancer (January 1995)
 Consuming olive oil only once a day or less—rr 1.25 for breast cancer (January 1995)

Dr. LIPPMANN. Mr. Chairman, there were two chest physicians on the panel. Dr. Wolff has recommended the views of one. The other one did not think that a better mechanistic understanding was essential. There are other M.D. epidemiologists on the panel, and I wrote a letter with some of them pointing out that while we certainly need to know a lot more about mechanism—and I am not able to tell you now what all of the mechanisms are—these M.D. epidemiologists did see a causal connection between particles in the air and the effect. We are gaining more information as we speak. The evidence is now accumulating to show more of a mechanistic basis for this.

I refer you to the staff paper where the letter that I signed with these other epidemiologist members is included as Appendix K. It lays out all the details and why we see a causal association.

[The referenced letter follows:]

March 19, 1996.

Hon. CAROL M. BROWNER, ADMINISTRATOR,
 U.S. Environmental Protection Agency,
 Washington, DC.

RE: SUPPLEMENT TO THE CLOSURE LETTER FROM THE CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE

DEAR MS. BROWNER: The co-signers of this letter are members of the Particulate Matter Criteria Document Review Panel and consultants to the Clean Air Scientific Advisory Committee (CASAC) of the Science Advisory Board, U.S. EPA. This letter is not being sent as a minority report to the CASAC closure letter, but as a supplement to address some of the concerns raised in the CASAC letter. We were selected

for the CASAC review of the Particulate Matter Criteria Document because of our combined expertise in the interpretation of epidemiological studies, our understanding of the literature on the human health effects of particulate air pollution, and our familiarity with the use of air monitoring data in analyzing human health effects. As individuals, we have been extensively involved in conducting studies of population exposure to air pollution and evaluating the human health effects of this exposure.

As noted in the closure letter to you on the draft Air Quality Criteria for Particulate Matter from the chair of CASAC, the Panel members praised the EPA criteria document for its excellent integrative synthesis of the literature. Overall, most panel members concluded that the document made a persuasive case that population exposure to particulate matter (PM) is casually associated with excess mortality and morbidity in the U.S. even at concentrations at and below the existing primary air quality standard. While the cosigners of this letter are in agreement with this judgment, we are aware that some of our Panel colleagues have reservations about this important conclusion. Our purpose in the supplementary letter is to make explicit our reasons for reaching our conclusion, in order to assist the staff of the National Center for Environmental Assessment in addressing the reservations of our colleagues. We also intend our comments to aid the staff of the Office of Air Quality Planning and Standards in preparing the staff paper in support of a revised particulate air quality standard.

The closure letter from the chair of CASAC notes that the concerns of Panel members who are not in full agreement with the above conclusion fall into three categories:

1. Uncertainties in the human health risks of particulate air pollution, arising from errors in air monitoring from estimating human exposure from central monitoring data, and from relating these data to excess mortality and morbidity.
2. Concern that the case for $PM_{2.5}$ being the best available surrogate for the principal causative agent in particulate air pollution may be overstated, and that EPA has not adequately justified its rejection of other alternative explanations.
3. Recently published studies that appear to contradict, or at least to present a different perspective on, the conclusions reached by EPA in its integrative synthesis of the literature.

Regarding the first of these concerns, the writers of this letter wish to make it clear that we are not arguing that $PM_{2.5}$ is the causal agent of the observed excess mortality and morbidity associated with particulate air pollution. In our judgment, the studies reviewed in the criteria document, specifically those considered in Chapter 12 (Epidemiological Studies), are persuasive in demonstrating a causal relationship between particulate air pollution, as measured by different methods in the various studies, and excess mortality and morbidity. However, the evidence does not allow us to conclude that a specific physical or chemical component of the particulate mass is clearly the responsible causal agent. Our conclusion is analogous to making the assertion that cigarette smoke is a cause of lung cancer and nonmalignant respiratory disease, even though the specific causal agent in cigarette smoke has not been identified among the many chemicals known to be present in cigarette smoke.

The reasons for concluding that particulate air pollution is causally related to excess mortality and morbidity have been well stated in the integrative synthesis (Chapter 13) of the criteria document. For heuristic purposes, we will summarize these reasons here, and cite locations in Chapter 13 where supporting sentences and paragraphs are presented:

- A large number (2) of epidemiological time-series studies have consistently found a statistically significant association between daily variation in particulates and total mortality in cities in the U.S., Canada, Latin America, the U.K. and continental Europe.

These findings argue against the associations being attributable to statistical sampling variation, i.e. the role of chance (Section 13.4.1.1).

- The results of these time-series studies cannot be attributed to the vagaries of statistical modeling (Section 13.4.3.2), nor to confounding by season or weather (Section 13.4.3.3).

- The results of the time-series studies cannot be attributed to other criteria air pollutants. The mortality effect of particulates is found whether or not other pollutants are present at elevated concentrations, though it is difficult to separate the effects of particulates from other pollutants when the latter covary with particulates. The most persuasive evidence that the causal agent is some component of the air-borne particulate mass is in studies of cities or seasons where other pollutants are present at very low concentrations. Across the range of the 20 studies mentioned above, particulate air pollution is the only pollutant that is consistently associated

with excess daily mortality, and the estimate of its effect is relatively stable when adjusted for the presence of co-pollutants. There are exceptions to this stability, particularly in those cities where particulate and gaseous air pollutants are highly intercorrelated. But no monitored air pollutant, other than particulate matter, can account for the consistently observed excess mortality in these studies (Section 13.4.3.4). Excess morbidity from cardiopulmonary diseases has also been observed in a considerable number of studies (Section 13.4.1.2), and the morbidity relationship with ambient particulate concentrations is stronger overall and more consistent than for any other air pollutant.

- There is considerable coherence between the observed mortality and morbidity effects of particulate air pollution. Not only is *excess* mortality from cardiovascular and respiratory diseases observed, but on days of higher particulates excess hospitalizations for cardiovascular and respiratory disease are reported. These mortality and morbidity excesses are strongest in populations that would be expected to be more susceptible to the effects of air pollution, particularly the elderly. The relation of particulates with mortality is strongest also for cardiopulmonary diseases rather than for other disease categories. On days of high particulates, there is an increased proportion of deaths from chronic obstructive pulmonary disease, pneumonia, heart disease and deaths among the elderly than on days of low particulates. These findings are supportive of a causal role for particulate air pollution, since they are health endpoints one would most anticipate from exposure by the inhalation route (Section 13.4.3.5 and Section 13.5.1).

Given the striking consistency of the above studies, their robustness to variations in statistical modeling, the coherence among different but closely related health endpoints, and the empirical elimination of any alternative explanation for the findings, we conclude that a causal interpretation for particulate air pollution exposure is reasonable and defensible. This conclusion is further supported by longitudinal cohort studies of populations in which a geographical gradient in particulate air pollution was associated with a corresponding gradient in total mortality, in cardiopulmonary mortality and in lung cancer. These studies carefully controlled for other individual risk factors for these health endpoints (Section 13.4.1.1).

With specific reference to the first category of concern expressed by the our Panel colleagues, although population exposure to air pollution cannot be perfectly estimated based on central monitoring, these inherent errors in exposure estimation are more likely to cause an underestimation of the adverse health effects associated with pollution exposure, particularly in longitudinal cohort studies where individual risk factors and exposures are directly related to health effects. Thus the consistent positive findings cannot be attributed to exposure measurement error. Furthermore, there is growing evidence that fine particles are more uniformly distributed over large geographic areas than are coarse particles (Section 13.2.4), that measurements at one site give a reasonable estimate of the fine particulate concentrations across a city (Section 13.2.6), and that fine particles penetrate and have longer lifetimes indoors than coarse particles (Section 13.2.6). This evidence supports using ambient measures of fine particulates at a central site as an acceptable estimate of the average exposure of people in the community (Section 13.2.6). For these reasons, we judge that uncertainties arising from air monitoring and human exposure estimation do not negate the consistent excess mortality and morbidity associations discussed above.

With regard to the second concern of our Panel colleagues, we believe that the case has been made that fine particulates, as measured by $PM_{2.5}$, are the best surrogate currently available for the component of particulate air pollution that is associated with excess mortality and morbidity. We emphasize once again that we are not claiming that $PM_{2.5}$ is the causal agent, but rather that $PM_{2.5}$ is a better measure, than any alternative metric, of the complex in the particulate mass that is causing excess mortality and morbidity. Distinguishing between PM_{10} and $PM_{2.5}$ is difficult, given the high correlation between these two pollutants in both time and space. In many studies, either metric will provide nearly the same estimate of the exposure-response relationship. However, a number of recent re-analyses of mortality and morbidity have been performed to address the issue of whether fine or coarse particulates (the latter indexed by subtracting $PM_{2.5}$ from PM_{10}) more consistently predicts a relationship with adverse health effects. These studies, as reviewed in Section 13.4.1.1 and Tables 13-3, 13-4 and 13-5 of the Criteria Document, conclude that excess mortality, hospital admissions for respiratory diseases and decreased lung function are more strongly and consistently associated with fine rather than with coarse mode particulates. These findings are also supported by earlier studies in the U.K. in which British Smoke measurements, which primarily reflect the contribution of the fine particle mode, were consistently associated with excess mortality. Finally, several characteristics of fine mode particles, as opposed to the coarse

mode, are more consistent with the observed excess mortality and morbidity observed in epidemiological studies. As noted earlier, these characteristics are: (1) fine particulates are more uniform in distribution than the coarse mode across urban areas, (2) fine particulates penetrate into indoor environments more completely than coarse particles, and (3) fine particulates have a more prolonged residence time in indoor air than coarse particles. These points are discussed in Section 13.7, Summary and Conclusions. Given that a causal association of excess mortality and morbidity with particulate air pollution has been established, we concur with staff's judgments that fine particulates are the best available surrogate for the population exposures associated with these health effects.

With regard to the third concern of our Panel colleagues, some studies have recently been published that are interpreted as contradicting the conclusion that particulate air pollution is causally associated with excess mortality and morbidity. We agree that, in its revision of the criteria document, EPA needs to address these apparent discrepancies more explicitly, and we offer the following comments to assist staff in that task.

First, the Health Effects Institute (HEI) reanalysis does not contradict any of the above conclusions. The HEI analysis conclusively demonstrated that the positive findings from the original studies selected for reanalysis were replicable, were not an artifact of statistical modeling, and were not confounded by idiosyncrasies in the method to control for season or weather. The HEI investigators then proceeded to apply their statistical modeling procedure to data from Philadelphia. They reported moderately high intercorrelations between particulates, as measured by total suspended particulate (TSP) measurements, and several of the pollutant gases, and, as expected, found that under these conditions, they could not attribute the observed exposure-response mortality relationships to TSP alone. They further observed that the TSP and SO₂ effects were not independent of one another, and that the TSP effect was stronger in some seasons of the year and at some concentrations of SO₂, while the SO₂ effect was stronger in other seasons and at some concentrations of TSP. The HEI investigators appropriately concluded that, because of the high intercorrelations between pollutants in Philadelphia, mortality effects could not be attributed solely to particulates. More importantly, in their further report on this phase of their study, they concluded that "insights into the effects of individual criteria pollutants can be best gained by assessing effects across locations having different pollutant mixes and not from regression modeling of data from single locations" ("Air Pollution and Mortality in Philadelphia, 1974-1988", interim report dated February 9, 1996). The EPA Criteria Document undertakes this assessment of effects across locations having different pollutant mixes, and this assessment was discussed above (in the third bulleted paragraph).

One published reanalysis (Moolgavkar S: *Epidemiology* 1995; 6:476-484) of the Philadelphia mortality data set has been interpreted as contradicting the findings of the original study (Schwartz J & Dockery DW: *Am. Rev. Resp Dis* 1992; 145:600-604), which concluded that particulates were positively associated with variations in daily mortality. However, the HEI reanalysis, reported above, confirmed the findings of the original study, but more importantly, noted that it was not possible in Philadelphia to attribute the mortality effect exclusively to particulates or individual gaseous pollutants, due to their high intercorrelations, as previously discussed. Separation of the effects of these pollutants requires analyses in a variety of locations with different pollutant mixes.

Presentations and papers by Lipfert and Wyzga (*Inhalation Toxicology* 1995; 7:671-689) discuss uncertainties in identifying responsible pollutants in epidemiological studies. This article raises the important issue of measurement error, but in applying its analysis to the Philadelphia data set, it encounters the same problem of intercorrelated pollutants and the inability to partition health effects exclusively or primarily to one of the pollutants. Similarly, the analysis of the Philadelphia data set by Li and Roth (*Inhalation Toxicology* 1995; 7:45-58) purports to show that a panoply of seemingly conflicting findings is produced with different modeling strategies, but this paper is superseded by the HEI report, which shows conclusively that the confounding effect of weather was appropriately controlled in the original analysis, and that the original results are not an artifact of the modeling strategy.

Finally, among papers considered as not supporting the main conclusion of the EPA criteria document, that of Styer et al. (*Environ. Health Perspec* 1995; 103:490-497) fitted separate regressions to each month of the year and found significant particulates effects only in a few of the months. But such partitioning of data in small time segments is considered to be inappropriate because it results in a significant loss of statistical power and thus a loss of sensitivity to the moderate relative risk associated with ambient air pollution and a loss of ability to separate the effects of one pollutant as opposed to another.

There are several reasons why the mortality and morbidity effects of particulate air pollution will not be the same in all cities and at all seasons of the year. Therefore, there will not be total agreement among all published studies in the magnitude of the adverse effect per unit of particulate exposure. The reasons for these variations in estimates of the exposure-response relationship are several (as discussed in Section 13.4.1.1): (1) the toxicity of particulates likely depends on size distribution and chemical composition, and these characteristics vary among geographic areas. (2) local populations differ in demographic and socioeconomic characteristics, and these differences will be likely to modify the health effects of particulate exposures. (3) the health status of communities differs among geographic areas, and thus the susceptibility of populations to the same level of particulate air pollution will vary. (4) average levels of copollutants will vary across geographic areas, and these may cause small or moderate variations in the particulate effect. In spite of these considerations, there is a remarkable consistency in the body of epidemiological studies, showing a positive exposure-response association between particulates and mortality and morbidity. In our judgment, EPA has appropriately synthesized this evidence and drawn a responsible public health conclusion, namely, that particulate concentrations at current levels are causally associated with excess mortality and morbidity. Furthermore, we agree that fine particulates, as currently indexed by $PM_{2.5}$, are the most appropriate indicator for the component of the particulate air mass to which these adverse effects are attributed. We also agree that some adverse health effects may be related to the coarse particulate mode, and that therefore it is desirable to consider fine and coarse mode particulates as separate candidates for air quality standards. This is the final conclusion of Chapter 13 of the Criteria Document, and we hope that our discussion will assist the EPA staff in presenting firmer support for their conclusion.

Sincerely,

MORTON LIPPMANN,
*Professor, Nelson Institute of Environmental Medicine,
New York University.*

CARL SHY,
*Professor and Chair, Department of Epidemiology,
University of North Carolina at Chapel Hill.*

JAN STOLWIJK,
*Professor, Department of Epidemiology and Public Health,
Yale University.*

FRANK SPEIZER,
*Professor, Channing Laboratory,
Harvard Medical School.*

Senator INHOFE. Thank you, Dr. Lippmann.

Let quote from this magazine for the benefit of the audience as well as committee members.

What does it take to make a study worth taking seriously? Over the years epidemiologists have offered up a variety of criteria, the most important of which are a very strong association between disease and risk factor in a highly plausible biological mechanism. The epidemiologists interviewed by *Science* say that they prefer to see both before believing the latest study, or even the latest group of studies. Many respected epidemiologists have published erroneous results in the past and say it is so easy to be fooled that it is almost impossible to believe less than stunning results.

In another article, Marsha Engle of the *New England Journal* stated, "As a general rule of thumb, we are looking for a relative risk of three or more."

And Robert Temple, who is with the FDA, the director of drug evaluation, has stated, "My basic rule is if the relative risk isn't at least three or four, forget it."

I would now ask Dr. Wolff this question. I understand in the studies the EPA relied on, the relative risk factor for the particulate matter studies was right around 1 or 1.2, since there is no identifiable biological mechanism—and I don't believe there is from what I have studied—and the risk factors are so low, in the words

of the Science magazine article, are these studies “less than stunning results”?

Dr. WOLFF. Mr. Chairman, there was tremendous diversity of opinion on the PM panel. I think part of that diversity of opinion was due to the members who considered the article that you referred to and essentially none of the studies that had been reported on the relationships between PM and mortality meet those criteria.

Senator INHOFE. Unfortunately, my time has expired. I had some questions.

Let me just ask both of you a question.

Do you think that there was adequate time—having to deal with the process—did the panel have enough time to weigh all the evidence? Or were deliberations rushed on this?

Dr. Lippmann.

Dr. LIPPMANN. Just a brief note.

Dr. Trichopoulos, who was cited in that article in Science—he said, when you have other information, you don’t need that large a relative risk. That is in the documentation also, and perhaps that should follow in the record.

As far as time, there is no question that the court-ordered deadline made it much more difficult. Dr. Wolff worked heroically, as did the EPA staff people, as did many members of the committee. So we did have the usual number of review sessions.

It would certainly always be desirable to have more time. However, the process did work, and we are always going to be left at the end of one of these review processes wishing we had more time and more information. But if the Clean Air Act calls for the standard to be fully reviewed—it was done. Lots of people worked very hard under the tight deadlines to see that it was done, but it got done.

[The referenced article follows:]

[From Science, Letters to the Editor, September 8, 1995]

THE DISCIPLINE OF EPIDEMIOLOGY

(By Dimitrios Trichopoulos)

In the Special News Report “Epidemiology faces its limits” (14 July, p. 164), Gary Taubes assembles a series of quotations from ourselves and others about potential methodologic pitfalls in epidemiologic studies that might leave readers with the misimpression that evidence based on epidemiologic findings is not usually credible.

A problem does exist with general media reports about single scientific studies. Such reports often herald new results without describing the scientific context, which can create unnecessary fear and confusion. However, this is more an abuse of epidemiologic evidence than a problem with epidemiologic research. Taubes seems to perpetuate this confusion by listing several media reports of published findings and telling the reader “you be the judge” (p. 156) when proper judging is impossible without substantial additional information. In any scientific field, findings of individual studies are usually not considered seriously until confirmed by others. Also, in epidemiology, as in any other scientific field, more powerful studies need to be conducted to evaluate smaller effects, where sources of bias may be especially problematic. Often, doing so will require large and long-term prospective studies with repeated measures of exposure based on both questionnaires and biological measurements; a substantial number of such studies have commenced over the last 15 years.

Taubes did not emphasize that what we do know about the prevention of cancer and cardiovascular disease has derived largely from epidemiologic findings. This knowledge includes not just the many adverse effects of cigarette smoking, but also the relation of overweight to many diseases, the benefits of increased physical activ-

ity for cardiovascular disease, the effects of many occupational exposures (such as benzene and asbestos), the relation of exogenous postmenopausal estrogens to cancer of the uterus, the relation of sunlight to all forms of skin cancer, the relation of ionizing radiation to many cancers, the adverse effects of many pharmacologic agents (for example, DES and thalidomide), and the protective effects of high intake of fruits and vegetables against many cancers.

Epidemiology has also provided important reassurance that many aspects of daily life are not major risk factors. For example, the relation between coffee consumption and coronary heart disease may not be completely settled, but the danger is minimal: The uncertainty is whether as much as five cups per day is a weak risk factor or not a risk factor at all.¹ Fear of saccharin carcinogenicity engendered by studies in rats was quelled by epidemiologic research. Furthermore, epidemiologic studies have provided clear evidence that the incidence of several other forms of cancer, including ovarian cancer, is lessened as a consequence of using birth control pills.

If we wish to continue our progress in understanding the importance of lifestyle and environmental risk factors, we have little choice but to monitor the occurrence of illness of persons who have and have not been exposed to such factors. As Bruce Ames, a molecular biologist at the University of California, has noted,² advances in other biological sciences can greatly add to the power of epidemiologic studies, but cannot replace them. Taubes's report is insightful and useful for epidemiologists and nonepidemiologists alike. However, I have two objections, one of them of personal nature, the other more general.

Taubes writes that I have expressed the view that only a fourfold risk should be taken seriously. This is correct, but only when the finding stands in a biological vacuum or has little or no biomedical credibility. We all take seriously small relative risks when there is a credible hypothesis in the background. Nobody disputes that the prevalence of boys at birth is higher than that of girls (an excess of 3 percent), that men have a 30 percent higher rate of death compared to women of the same age, or that fatality in a car accident is higher when the car is smaller.

The more general issue is that Taubes has omitted a consideration that is of a paramount importance in any scientific argument. Epidemiology should be evaluated in comparison to other disciplines that serve the same objective, that is, to identify the causes of human disease and facilitate their prevention. Among these disciplines, only epidemiology can document causation without concern about dose-extrapolation or species variability and with built-in accounting for potential modifiers.

It could be said for epidemiology, with respect to disease etiology and prevention, what is frequently said about democracy as a system of government: They both have many problems and weaknesses, but they still represent the best available approach for the achievement of their respective objectives.

(By Jerry Rapp)

Taubes's excellent article about the proliferation of health-related messages to the public, and in particular the role of the popular press in their promulgation, misses one factor driving this process. Research institutions are eager to have the results of health risk factor studies performed in their laboratories appear in prominent newspapers and news magazines. This is so because individual philanthropists like almost nothing better than to support institutions whose research efforts have appeared on page one, of, say, the *New York Times*. With the deceleration in government funds available for research and the concomitant increased dependence on private, and especially individual, funding sources, there will likely be an acceleration of these sorts of articles appearing in the popular press. It would generate far less confusion if they were just left in the scientific literature.

(By Robert W. Miller)

The limits of epidemiology for environmental studies are well covered by Taubes. Genetic epidemiology is quite a different story. Clustering of cancer in families has led to the recognition of tumor suppressor genes by Alfred G. Knudson Jr. through study of retinoblastoma in childhood.³ These genes have since been found in other cancers of children and some of the commonest cancers of adults. Epidemiologic identification of the diverse familial cancers that cluster in Li-Fraumeni syndrome

¹ S. Greenlang, *Epidemiology* 4, 366 (1993).

² B.N. Ames, *Science* 221, 1256 (1983).

³ A.G. Knudson Jr., *Proc. Nat'l. Acad. Sci. U.S.A.* 68, 820 (1971).

led to laboratory research that has furthered understanding the role of the p53 gene in carcinogenesis.⁴ New clues of the origins of neoplasia are also coming from laboratory studies based on cancer clusters in heritable disorders, such as ataxia-telangiectasia.⁵ Genetic epidemiology should not suffer guilt by association with the downside of its environmental counterpart.

(By Alfred J. Saah)

When critics of epidemiology pay homage at the altar of the randomized clinical trial, such trials are made to sound only moderately troublesome compared to observational studies, when in fact they are often absolutely impractical or absolutely unethical. Examples include randomizing women to method of birth control and individuals to diet.

For such research, observational studies are the only recourse if you want to work with humans. The future and power of epidemiology rest not with simply self-reported data, but with combining such information with molecular data on susceptibility. In this way, risk measurements reflect characteristics of both host and environment and make targeting prevention strategies rational. The challenge will be to use these host factors, such as genetic data, in a socially acceptable and nonpunitive fashion. Then epidemiology will provide truly meaningful and relevant estimates of risk.

(By Gio Batta Gori)

Most of the epidemiology of multifactorial diseases fails a test of method, due to absent experimental randomization and unachievable control of biases and confounders. In general, it also fails the ultimate test of predictivity, as large randomized experiments designed to verify major observational inferences have been thoroughly disappointing.⁶ Now, a resounding admission of impotence threatens our survival and demands remedial measures.

As other professionals have done, epidemiologists could establish a code of good practice, spelling out optimal standards of hypothesis formulation, study design, and conduct. Structural uncertainties should limit heuristic causal inferences to relative risk or odds ratio values above 3 or 4, as Trichopoulos (quoted in the article by Taubes) and others before him have concluded.⁷ Although still short of assuring verification, this last provision would link with *de minimis* considerations of ongoing regulatory reform.

Epidemiologist have no choice but to warrant their credibility. We owe it to society and to the young entering the profession, who need to know honestly whether they can make a difference. Too much of epidemiology has become predictable advocacy without secure philosophical foundations. A code of good epidemiologic practice would be a beginning, perhaps after some soul-searching about the morality of provoking public anxieties and policies based on essentially unverifiable conjectures.

Dr. WOLFF. The objective of the review is to try to reach consensus on the issues. One of the reasons why we couldn't was because we were so rushed. Normally, this is a process that takes place over a number of years. The PM was compressed in a little over a year. I certainly think that it had an adverse effect on the process.

Senator INHOFE. Did CASAC recommend more research?

Dr. WOLFF. CASAC recommended more research.

Senator INHOFE. Senator Chafee.

Senator CHAFEE. Thank you, Mr. Chairman.

⁴D. Malkin et al., *Science* 250, 1233 (1990).

⁵K. Savitsky et al., *ibid.*, 268, 1749 (1995).

⁶M. Susser. *Epidemiol. Rev.* 7, 147 (1985); L. Werko, *Acta Med. Scand.* 221, 323 (1987); MRFIT Group. *J. Am. Med. Assoc.* 263, 1795 (1990).

⁷N.E. Breslow and N.E. Day, *Statistical Methods in Cancer Research*, vol. 1. The Analysis of Case-Control Studies International Agency for Research on Cancer, Publ. No. 32, Lyon, France, 1980; K.J. Rothman, in *Cancer Epidemiology and Prevention*, D. Schottenfeld and J.F. Fraumeni, Eds. (Saunders, Philadelphia, PA, 1982), pp. 15-22, E.L. Wynder, *Prev. Med.* 16, 139 (1987).

Dr. Lippmann, Dr. Wolff made the following statement regarding ozone: there is no bright line, no threshold, the scientific community made great strides, but—what do you say about that? Do you find a bright line here?

Dr. LIPPMANN. No, there is no bright line. There is no threshold. My own studies with normal children, asthmatic children, healthy people doing their jogging show that the higher the ozone the greater the drop in lung function. The only thing you can do is to say is that if you are dealing with the issue of adversity then greater than 10 percent, or greater than 20 percent loss of function is an adverse effect. But you can't get away from there being a measurable response at any ozone concentration above background.

The exposure chamber studies show that there is also lung inflammation going on while the function is changing. So the Administrator is obligated to consider all of the measurable responses in making her judgment.

What can't be disputed is that there is an exposure-response relationship. If you divide up the cells from the chart—as in the example from the staff paper letter to which Dr. Wolff referred—you can say there is no significant difference between one form of the standard and another because of the uncertainty around each of them. But it is indisputable that if you lower the permissible exposure you get less response in terms of function, hospital admissions for cardiopulmonary diseases, and even mortality.

Senator CHAFEE. I think a subsequent witness is going to have a chart showing New York City hospital admissions. I am not going to ask you about that. I will wait.

Dr. LIPPMANN. That is kind of the chart I was referring to. But you will also hear today from Dr. Thurston, whose research is the basis for that chart. I think Dr. Thurston will tell you that the chart doesn't necessarily represent what the research behind it says.

Senator CHAFEE. I don't want to get into the chart yet. It is what we say in the trade, a very busy chart.

[Laughter.]

Senator CHAFEE. Dr. Wolff, EPA's proposed standards for PM_{2.5} is a major undertaking. It is my understanding that it is probably the largest single regulation EPA has ever proposed. I guess my question to you is: do you think the science is adequate to support that standard?

Dr. WOLFF. There was no consensus as to what the level should be on the committee. The ranges of recommendations ranged from the lower end of EPA's recommendations to higher than EPA's range.

Senator CHAFEE. Higher than the 2.5?

Dr. WOLFF. The upper end of the range for 2.5 was 65 micrograms per cubic meter. Some of the members recommended a level that was higher than that. So I don't think you can say that CASAC's conclusions support the level that EPA selected. I don't think you could say that CASAC's conclusions support any level.

Senator CHAFEE. Am I correct that you did not support the PM_{2.5}?

Dr. WOLFF. That is not true. I supported a 2.5 standard.

Senator CHAFEE. We get into this back and forth on more time—which you both testified to that you think more time would have been very valuable. Dr. Lippmann has indicated that no matter how much time you get, you probably want more. But is the science within reach? Do you have that feeling, Dr. Wolff? How much longer would it take to get the science that you feel would be necessary if we made those scientific studies a high priority right now and gave it the money that you think it should have?

Dr. WOLFF. Based on our experience with the review, I think we can frame the questions that need to be addressed in the near term. Unfortunately, we don't have very many measurements of PM_{2.5} right now. We are going to need those measurements before we can answer those questions. My own personal feeling is that we're talking about a 5-year timeframe to find answers to those questions.

Senator CHAFEE. Let me see if I understand the answer.

Did you say 5 years?

Dr. WOLFF. I think we need 5 years before we have answers to those questions. It is our hope that we have answers to those questions before we begin the next review cycle.

Senator CHAFEE. And you nodded in agreement, Dr. Lippmann?

Dr. LIPPMANN. Yes, 5 years can answer many of these questions. I am sure there will be some that have further questions 5 years down the road. But 5 years is a minimum time to have a considered, well-designed, well-executed program. Lab work and epidemiological studies take a long time to do and a long time to analyze. It takes a long time to go through peer review. I would say that 5 years is a good timeframe.

Senator CHAFEE. I see my time is up. Thank you, Mr. Chairman.

Senator INHOFE. Thank you, Senator Chafee.

Senator BAUCUS.

Senator BAUCUS. Thank you, Mr. Chairman. I will be very brief.

I would like to establish what CASAC did agree on. If I understand it, CASAC agreed with respect to ozone, that there should be a change from a 1-hour average to an 8-hour average. Is that correct?

You are both nodding affirmatively.

Dr. LIPPMANN. That is correct.

Dr. WOLFF. It was the consensus of the committee.

Senator BAUCUS. Again with respect to ozone, I understand that the CASAC panel agrees that the studies EPA has collected provide an adequate basis for making a decision on the standard. Is that correct or not?

Dr. LIPPMANN. The studies that EPA selected and winnowed through the CASAC process were the right studies to consider. We all wish we had more information.

Senator BAUCUS. Does it provide an adequate basis for making a decision?

Dr. LIPPMANN. Yes. The Administrator is required to look at the evidence at some given point in time. There was much more evidence than we had last time we reviewed ozone when I chaired CASAC in the 1980's. We have much more information and a judgment call was possible. It wasn't all of the evidence we would have liked to have.

Dr. WOLFF. We agree it was the appropriate evidence. It was the available evidence. But we did not conclude that it gave us a bright line.

Senator BAUCUS. I understand.

Let me move to PM, because I understand your earlier testimony, Dr. Wolff—that there is no consensus on the level or time, yet there is a consensus on a new 2.5 standard.

Dr. WOLFF. That's correct.

Senator BAUCUS. I am sure you agree, Dr. Lippmann?

Dr. LIPPMANN. Yes, sir.

Senator BAUCUS. The panel did agree that a new 2.5 standard is needed?

Dr. LIPPMANN. Yes, when you control PM₁₀, what industry and everyone else does is control the mass, which is driven by the largest particles. So the controls directed at PM₁₀ have had very little effect on fine particle concentration. We need a fine particle standard in order to have controls directed at getting fine particle concentrations down.

Senator BAUCUS. And with respect to PM₁₀, the panel agrees that either a daily or an annual standard should be established?

Dr. WOLFF. With PM₁₀?

Senator BAUCUS. No, 2.5. I'm sorry.

Dr. WOLFF. Either a 24-hour or annual standard could be designed to protect long-term or short-term exposure.

Senator BAUCUS. But is it could be? Or should be?

Dr. WOLFF. Could be is the answer.

Senator BAUCUS. What is the alternative if not a daily or annual? Hourly? What are you going to come up with?

Dr. WOLFF. I think there was consensus that it should either be annual or 24-hour.

Senator BAUCUS. Is that right, Dr. Lippmann?

Dr. LIPPMANN. Either or both. Most of us endorsed both.

Senator BAUCUS. Concerning the additional time needed, are you saying that 5 years is needed before the EPA should promulgate proposed PM standards? What does the 5 years refer to?

Dr. LIPPMANN. I think we both agree that something will be done this round because there is a time clock and the Administrator has to take an action. We are saying that we are very unhappy that we don't have better information. The timeframe for getting that better information is not a month or a year. We are not going to get much that will help us in another month or another year. Let the clock go around to the next cycle and put in place the means to get that information.

Senator BAUCUS. But what do we do in the meantime to the proposed standards that EPA has promulgated?

Dr. WOLFF. A number of CASAC members expressed the view that we should set a PM_{2.5} standard at this time, but at a level that is approximately equivalent in stringency to the present PM₁₀ standard. This would allow us to begin to collect the data so that we have the data and can make a mid-course correction 5 years from now.

Senator BAUCUS. What would be the average midpoint of the range of the panel with respect to what we should do with respect to PM_{2.5}?

Dr. LIPPMANN. As Dr. Wolff said, the panel's personal preferences span the entire spectrum of the range that EPA proposed.

Senator BAUCUS. Expand the entire spectrum?

Dr. LIPPMANN. That's right. So the Administrator was left with having to make her own judgment call.

Senator BAUCUS. My question is, What would CASAC's recommendation be?

No, let me ask you personally, what your personal view would be on that question.

Dr. Lippmann.

Dr. LIPPMANN. I think what the Administrator has proposed is a prudent step in the right direction. My personal preference would have been for a somewhat more stringent level. But I recognize all the uncertainties that Dr. Wolff gives greater importance to and that we can't turn the atmosphere around right away. If we are moving in the right direction and have to look at it again in 5 years, that is fine.

Senator BAUCUS. So even though we have less than perfect knowledge, your view is that although it could be more stringent, the proposed regulation is very reasonable?

Dr. LIPPMANN. That's correct.

Senator BAUCUS. Dr. Wolff.

Dr. WOLFF. My personal feeling would be to set the standard approximately equivalent to today's PM₁₀ standard and then be able to look at it 5 years from now to see if that needs to be changed. The reason I would err on the high end is because right now there are mechanisms in place that are causing PM to decline. PM will decline for the foreseeable future, even without new control measures at this point.

Senator BAUCUS. But do you personally find the proposed regulation reasonable?

Dr. WOLFF. I can't endorse the present proposal based on what I have seen.

Senator BAUCUS. What would a reasonable person conclude—we have a big range here—could an objective scientist find that this is reasonable? Would an objective scientist find this reasonable?

Dr. WOLFF. I think a reasonable position would be to set the standard—

Senator BAUCUS. Would an objective scientist find this reasonable?

[Laughter.]

Dr. WOLFF. I would think a reasonable scientist would go a little bit higher.

Dr. LIPPMANN. I think the choice made is certainly reasonable.

Senator BAUCUS. And a reasonable scientist would find it reasonable?

Dr. LIPPMANN. Most of the committee would have found that it would be reasonable.

Senator BAUCUS. Thank you.

Senator INHOFE. They are both very reasonable and very objective.

[Laughter.]

Senator INHOFE. Senator Sessions.

Senator SESSIONS. Dr. Wolff, I guess you consider yourself a reasonable scientist?

Dr. WOLFF. Yes, I do.

Senator SESSIONS. I was a little confused, and perhaps I missed something there.

I believe you indicated to Senator Chafee that you favor the 2.5 standard. Then I thought you said that you indicated that you would prefer leaving it at 10. Can you explain that for us, please?

Dr. WOLFF. Out of the 21 CASAC members, 19 favored the creation of a new standard for PM_{2.5}. I was one of those 19 who made that recommendation. All 21 members favored retention of the current PM₁₀ standard. I was one of those as well.

Senator SESSIONS. Dr. Lippmann, with regard to the new methodology—the 8 hours and all—can you give us your impression about how much that eases the implementation or the drop?

Dr. LIPPMANN. It doesn't. It changes in those areas of the country which did have more of a sharper peak of ozone in the afternoon. It is a relaxation. For those who tended—like in your part of Alabama—to have a broader daily peak, it tends to be more restrictive. But 90 ppb on an 8-hour average is about the same as 120 ppb for one hour.

What relaxes it and makes it less likely to cause a spurious exceedance, is going from a single exceedance being evidence of exceedance to the third highest. So the really unusual weather day won't cause a community to go out of exceedance. The big advance is not only in changing the hours over which you average it, but in looking at multiple exceedances. This has been done for both PM_{2.5} and for ozone.

Senator SESSIONS. With regard to the Birmingham study, have you seen a counter-study that suggested that had humidity been factored in that a different result would have occurred on the mortality rates?

Dr. LIPPMANN. If you look at this literature, which is voluminous, there is all kinds of conflicting information. Most respected people in this field, having looked at weather, do not find that humidity or temperature account for these factors. You can, however, find some studies that come to different conclusions.

Senator SESSIONS. In particular, with regard to the Birmingham study, there was a study that said that there would be no increase in mortality had they factored in humidity.

Dr. LIPPMANN. Yes, there is a published study.

Senator SESSIONS. EPA has not been able to have the resources or otherwise to study that and to make a definitive decision as to which one of those studies might be correct?

Dr. LIPPMANN. Yes, that is true, but EPA could not do it even if they had resources because it is a matter of flawed data in the models. It is hard to make a definitive judgment on the basis of one community and two different interpretations of data sets. This is a national problem and those issues are best addressed by looking not only at Birmingham—not ignoring Birmingham—but in a variety of communities to see where the dust shakes out.

Senator SESSIONS. We are a very high humidity State with the highest rainfall in the country. It makes a difference. That is a factor which would concern me.

Dr. Wolff, do all the members of the committee agree that the studies that are available to the committee form an adequate basis for a decision at this time?

Dr. WOLFF. Are you referring to ozone or PM?

Senator SESSIONS. Both.

Dr. WOLFF. The committee agrees that EPA has summarized the relevant studies. However, the committee, in the case of ozone, believes the science does not give us guidance as to what to select for a level. We state that it is strictly a policy decision.

For the PM, there is no agreement among the members as to what exactly the science says. So again, there is agreement that it is a policy call.

Senator SESSIONS. Dr. Wolff, recently a doctor in Scientific American dealt with the acid rain question and particulate matter in the atmosphere. Are you familiar with that article that has come out in the last few months?

Dr. WOLFF. No, I am not.

Senator SESSIONS. The article dealt with the impact. It sort of deals with unintended consequences of our actions. In the December 1996 issue, the conclusion in effect was that the reduction in particulate matter in the atmosphere—which is in effect a base that neutralizes acid rain—had substantially essentially neutralized the effect of our efforts to reduce acid rain. That had not been anticipated. As a matter of fact the author concluded, “When we began this work, we certainly did not anticipate that reducing one form of pollutants, dust particles, could be found to decrease the success or reductions or another pollutant, sulfur dioxide.”

I guess I am saying to you that if we knew within the scientific community what kinds of particles caused what kinds of medical problems, could we perhaps be more effective and make a better case for reduction of those particles as opposed to others that may not be harmful?

Dr. WOLFF. There are literally hundreds of different chemicals in the atmosphere that form these particles. Many people have suggested that maybe it is not the total number of particles. Maybe it is some constituent in the particles that causes the effects. You are absolutely right that we need more information.

Senator INHOFE. Thank you, Senator Sessions.

Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

Dr. Wolff and Dr. Lippmann, thank you both for your testimony and for your service.

This is confusing for us to try to understand and so important. I just want to clarify something because I was confused at the outset—and maybe some of my colleagues were as well—we are talking about two different kinds of measurement in particulate matter, aren't we? To state it in laymen's language, the size of the particles is what we ought to be concerned about. I think you said, Dr. Wolff, that 19 out of the 21 on CASAC agreed that we ought to go from the PM₁₀ standard down to 2.5 to measure finer particles, right?

Dr. WOLFF. Let me try to explain this. The PM₁₀ refers to particles that have a diameter of 10 microns and less. So it includes everything from 10 down. PM_{2.5} includes all the particles with a di-

ameter of 2.5 microns and down. So $PM_{2.5}$ is a subset of PM_{10} . It is finer.

Senator LIEBERMAN. But we have used the word standard interchangeably. I think that is where I got confused.

On what you just described, then, there was broad consensus on CASAC? Where there was disagreement and no consensus was what level of those 2.5 particles was acceptable in a unit of air. Is that correct?

Dr. WOLFF. That is correct.

Senator LIEBERMAN. On that there was disagreement, but I take it that you felt—and some of the epidemiologists who joined you in the letter Dr. Lippmann—that the standard the Administrator set was an appropriate standard to protect health.

Dr. LIPPMANN. Not quite. What we talked about in our letter was the plausibility of the association between the inhaled fine particles and the health effects. That letter was written before the Administrator made her choice of the concentration limit.

Senator LIEBERMAN. So the conclusion of those who wrote the letter was what about the plausibility?

Dr. LIPPMANN. As compared to Dr. Wolff and some other cluster of members on the panel, we were more convinced that the fine particles were causally associated with the health effects.

Senator LIEBERMAN. Still on particulate matter as opposed to ozone, Dr. Wolff, I have a photocopy of an article of July 14, 1996, from the Riverside (CA) Press Enterprise about this issue. You are quoted in the article as saying,

Something is killing Americans, but I don't know what. It's clear we need some kind of standard to prevent the effects we're seeing. The question is: What is it in the particulate matter that's doing it? The conclusion we come to is we don't know. That's the dilemma.

Is that a fair quote?

Dr. WOLFF. It was an accurate quote. That was somewhere during the middle of the review.

What was the date on that?

Senator LIEBERMAN. July 14, 1996.

[The referenced article follows:]

[From the Riverside (CA) Press Enterprise, July 14, 1996]

SOMETHING IS KILLING AMERICANS

(By Gary Polakovic)

Can the brown haze on the horizon really contain enough poisons to kill people? Overwhelmingly, scientists who study the problem say yes. Dozens of health studies from around the world in the past few years have convinced experts smog can be deadly in concentrations common in many communities.

Most experts believe particles are to blame. And there is wide-spread agreement air quality standards do not protect people from the danger.

"It's the single biggest public health problem we face today in the environment," said Daniel B. Menzel, chairman of the Department of Community and Environmental Medicine at the University of California, Irvine.

The U.S. Environmental Protection Agency twice reached the same conclusion about air pollution in two separate comparative risk reviews in 1987 and 1990 that predate the most incriminating particle pollution health studies.

Even industry scientists, skeptical at first, acknowledge a menace lurks in the air, although they caution against alarm and have concerns about proposals to crack down on smoggy particles.

“Something is killing Americans, but I don’t know what,” said George T. Wolff, principal scientist at General Motors and chairman of EPA’s Clean Air Science Advisory Committee. “It’s clear we need some kind of standard to prevent the effects we’re seeing.

“The question is: What is it in the PM (particle matter) that’s doing it? The conclusion we come to is we don’t know. . . . That’s the dilemma,” he said.

Therein lies the rub. It is the questions, not the answers, raised by the particle smog health studies that has embroiled scientists in debate over how air pollution kills.

The controversy centers on particle pollution and is reminiscent of a similar public health debate a few decades ago.

“It’s like the debate over cigarette smoking years ago,” said Morton Lippmann, professor of environmental medicine at the New York University Medical Center. “It is real, we just don’t know why it is happening.”

For example, scientists do not know which particles in the smog mix harm people. Several health studies implicate particulate matter sized 2.5 microns, called PM_{2.5}. But some scientists say it may be particles much smaller.

Others say it might be a particular particle, such as a metal fragment or sulfates. Still others wonder if particles work in concert with other pollutants to wreak harm. And a few say it may be impossible to distinguish which smog ingredient kills.

Few laboratory tests have been done to see whether particle-induced mortality documented in human populations can be reproduced using animals, an important step to provide a cause and effect relationship.

“I have no doubt we are seeing mortality, but so far no one has been able to identify a biologically plausible mechanism,” Menzel said.

Michael Kleinmann, toxicologist at the UC Irvine Air Pollution Health Effects laboratory, said recent tests at Harvard University and UC Irvine have begun to close that gap.

In an experiment concluded in April, Kleinmann found elderly rats breathing very tiny particles and a smidgen of ozone showed 30 percent more chemicals inside their lungs capable of destroying lung tissue and seriously compromising the animals’ respiratory health.

The uncertainties bother skeptics. Chief among them is Suresh Moolgavkar, epidemiologist at the University of Washington and professor at the Fred Hutchinson Cancer Research Center in Seattle. He acknowledges smog is deadly, but he said more research is needed to prove particles are solely responsible for premature death.

He showed that in Philadelphia gaseous sulfur oxide was associated with death during winter and spring while particles seemed to kill in summer. Sulfur oxide gas is emitted by coal-fired power plants and converts to sulfate, the most abundant particle pollutant in the East.

“If two individuals, one who ingested sugar laced with strychnine and one who took sugar laced with cyanide, dropped dead, would we blame the sugar?” Moolgavkar said.

But other scientists dispute those objections.

In a March 20 letter, four scientists told EPA Administrator Carol M. Browner that health studies clearly show “a causal relationship between particulate air pollution . . . and excess mortality and morbidity.” The letter was signed by Lippmann; Carl Shy, chairman of the Department of Epidemiology at the University of North Carolina at Chapel Hill; Frank Speizer, professor at the Harvard University Medical School; and Jan Stolwijk, epidemiology professor at Yale University.

The four scientists serve on an obscure, 21-member panel called the Clean Air Science Advisory Committee, which in May completed a review of the scientific evidence and endorsed EPA’s recommendation to create a new national standard to control ultrafine particles.

Authors of studies showing deadly effects of particles are also troubled by their findings, but for different reasons.

“It bugs us,” said C. Arden Pope III, researcher at Brigham Young University. “We’re not out to prove everyone is dying from air pollution. We keep asking ourselves, ‘Is it real?’ I was not a believer at all. I’ve tried for 10 years to try and explain away these effects, but the bottom line is the phenomenon remains.”

Jonathon M. Samet, chairman of the epidemiology department at Johns Hopkins University in Maryland, said doubts about harm from particles have largely been laid to rest. He led an investigation for the prestigious Health Effects Institute, which in August validated leading studies that conclude particles kill. The institute, funded by industry and federal funds, is widely viewed as an objective arbiter of such disputes.

As debate intensifies, Menzel at UC Irvine cautions scientists must not lose sight of the big picture: "We've still got a body count and we shouldn't be having that at all."

Senator LIEBERMAN. The question I would have—and this is our difficulty here—you agree something is killing Americans? Premature mortality—

Dr. WOLFF. I don't agree with that today. I don't agree that we have the basis to make that statement today.

We all went through a learning curve, to some degree, during this review. Personally myself, I went into the review with a very open mind. Along the way, my mind changed. By the time we had finished the review, I had more doubts as to whether or not the science supported the statistical relationship or the causality than I did when I started.

Senator LIEBERMAN. So did you then conclude, or do you know, that there are no premature deaths of Americans due to particulate matter?

Dr. WOLFF. I don't think we know.

Senator LIEBERMAN. So you really question the fundamental proposition about health effects in the EPA Administrator's report that 40,000 may be dying earlier than they would otherwise in this country?

Dr. WOLFF. There are a number of us on the committee who question that.

Senator CHAFEE. You're talking strictly particulates?

Senator LIEBERMAN. Yes, just particulates. That is what the 40,000 premature deaths was related to.

Dr. Lippmann, I take it that you do not question that there are some Americans dying prematurely because of these particles in the air?

Dr. LIPPMANN. I think more of the committee believes that they are.

Senator LIEBERMAN. And you are in that group?

Dr. LIPPMANN. Yes.

Senator LIEBERMAN. Was there a breakdown—did more of the epidemiologists, that is, public health experts on the committee, agree that there are premature deaths in America caused by particulate matter?

Dr. LIPPMANN. Yes.

[The letter and table referenced in the CASAC report follow:]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 13, 1996

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-CASAC-LTR-96-008

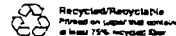
Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M. Street SW
Washington, DC 20460

Subject: Closure by the Clean Air Scientific Advisory Committee (CASAC) on the Staff Paper for Particulate Matter

Dear Ms. Browner:

The Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB) has held a series of public meetings during its peer review of the Agency's draft documents which will form part of the basis for your decision regarding the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM). The Committee has held public meetings on December 12-13, 1994 (planning and introductory issues); August 3-4, 1995 (review of the initial draft Criteria Document); December 14-15, 1995 (review of the revised draft Criteria Document and the first draft of the Staff Paper); February 29, 1996 (review of the revised draft Criteria Document - specified chapters only, and the Office of Air Quality Planning and Standards (OAQPS) Risk Assessment Plan); and May 16-17, 1996 (review of the revised draft Staff Paper). The primary Agency draft documents that we have reviewed are the: a) *Air Quality Criteria for Particulate Matter* (the "Criteria Document" prepared by the National Center for Environmental Assessment - Research Triangle Park, NC - ORD), b) *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (the "Staff Paper" prepared by the Office of Air Quality Planning and Standards - Research Triangle Park, NC - OAR), and c) *A Particulate Matter Risk Analysis for Philadelphia and Los Angeles* (draft), 1996. Prepared by Abt Associates for US EPA.

As part of our review process, we have kept you informed of our findings through three letter reports: a) *Clean Air Scientific Advisory Committee (CASAC) Comments on the April 1995 draft Air Quality Criteria for Particulate Matter* (EPA-SAB-CASAC-LTR-95-005; August 30, 1995); b) *Clean Air Scientific Advisory Committee (CASAC) Comments on the November, 1995 Drafts of the Air Quality Criteria for Particulate Matter and the Review of the National Ambient Air Quality Standards for Particulate*



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Matter: Policy Assessment of Scientific and Technical Information (OAQPS Staff Paper), (EPA-SAB-CASAC-LTR-96-003, January 5, 1996), and c) Closure by the Clean Air Scientific Advisory Committee (CASAC) on the draft Air Quality Criteria for Particulate Matter (EPA-SAB-CASAC-LTR-96-005, March 15, 1996).

The Clean Air Scientific Advisory Committee, supplemented by a number of expert Consultants (hereinafter referred to as the "Panel"), reviewed a first draft of the Staff Paper for Particulate Matter at the December 14 and 15, 1995 meeting in Chapel Hill, NC. At that meeting and in subsequent written comments by individual members which were provided to EPA Staff, the Panel made numerous recommendations for improving the draft document. The Panel met again on May 16, 1996 in Chapel Hill, NC and on May 17, 1996 in Research Triangle Park, NC to review a revised draft of the Staff Paper and the recommendations contained within the Staff Paper for the level and form of the proposed PM NAAQS. This letter is a summary of our findings and conclusions from that meeting.

It was the consensus of the Panel that although our understanding of the health effects of PM is far from complete, the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards. Seventeen of the twenty-one Panel members voted for closure. There were two no votes, one abstention, and one absence. However, most of the members who voted for closure did so under the assumption that the Agency would make significant changes to the next version of the Staff Paper which is due by July 15, 1996 (a court ordered mandate). The desired changes have been articulated to your staff at the meeting and subsequently in writing.

The Panel endorses the EPA Staff's recommendation not to establish a separate secondary PM NAAQS for regulating regional haze and agrees that there is an inadequate basis for establishing a secondary NAAQS to reduce soiling and material damage effects.

The attached table (Table I) summarizes the Panel members' recommendations concerning the form and levels of the primary standards. Although some Panel members prefer to have a direct measurement of coarse mode PM ($PM_{10-2.5}$) rather than using PM_{10} as a surrogate for it, there is a consensus that retaining an annual PM_{10} NAAQS at the current level is reasonable at this time. A majority of the members recommend keeping the present 24-hour PM_{10} NAAQS, at least as an option for the Administrator to consider, although those commenting on the form of the standard strongly recommended that the form be changed to one that is more robust than the current standard. There was also a consensus that a new $PM_{2.5}$ NAAQS be established, with nineteen Panel members endorsing the concept of a 24-hour and/or an annual $PM_{2.5}$ NAAQS. The remaining two Panel members did not think any $PM_{2.5}$ NAAQS was justified. However, as indicated in Table I, there was no consensus on the level, averaging time, or form of a $PM_{2.5}$ NAAQS. At first examination of Table I, the diversity of opinion is obvious and appears to defy further characterization. However,

the opinions expressed by those endorsing new $PM_{2.5}$ NAAQS can be classified into three broad categories. Four Panel members supported specific ranges or levels within or toward the lower end of the staff's recommended ranges. Seven Panel members supported specific ranges or levels near, at, or above the upper end of staff's recommended ranges. Eight other Panel members declined to select a specific range or level, but most had comments which appear as footnotes in Table I.

A number of Panel members based their support for a $PM_{2.5}$ NAAQS on the following reasoning: there is strong consistency and coherence of information indicating that high concentrations of urban air pollution adversely affect human health, there are already NAAQS that deal with all the major components of that pollution except $PM_{2.5}$, and there are strong reasons to believe that $PM_{2.5}$ is at least as important as $PM_{10-2.5}$ in producing adverse health effects.

Part of this diversity of opinion can be attributed to the accelerated review schedule. While your staff is to be highly commended for producing such quality documents in such a short period of time, the deadlines did not allow adequate time to analyze, integrate, interpret, and debate the available data on this very complex issue. Nor does a court-ordered schedule recognize that achieving the goal of a scientifically defensible NAAQS for PM may require iterative steps to be taken in which new data are acquired to fill obvious and critical voids in our knowledge. The previous PM NAAQS review took eight years to complete.

The diversity of opinion also reflects the many unanswered questions and uncertainties associated with establishing causality of the association between $PM_{2.5}$ and mortality. The Panel members who recommended the most stringent $PM_{2.5}$ NAAQS, similar to the lower part of the ranges recommended by the Staff, did so because they concluded that the consistency and coherence of the epidemiology studies made a compelling case for causality of this association. However, the remaining Panel members were influenced, to varying degrees by the many unanswered questions and uncertainties regarding the issue of causality. The concerns include: exposure misclassification, measurement error, the influence of confounders, the shape of the dose-response function, the use of a national $PM_{2.5}/PM_{10}$ ratio to estimate local $PM_{2.5}$ concentrations, the fraction of the daily mortality that is advanced by a few days because of pollution, the lack of an understanding of toxicological mechanisms, and the existence of possible alternative explanations.

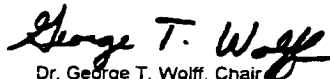
In recommending that the staff carry out a risk assessment, it was the expectation of CASAC that the risk assessments would narrow the diversity of opinion by evaluating how all of the uncertainties propagate throughout the entire model. However, not all of the uncertainties could be included and the combined effect of all of them could not be examined. The Panel recommended that additional analyses be conducted to present combined uncertainties. However, currently the risk assessments are of limited value in narrowing the diversity of opinion within the Panel.

The Panel is unanimous, however, in its desire to avoid being in a similar situation when the next PM NAAQS review cycle is under way by a future CASAC Panel. The Agency must immediately implement a targeted research program to address these unanswered questions and uncertainties. It is also essential that we obtain long-term PM_{2.5} measurements. CASAC is ready to assist the Agency in the development of a comprehensive research plan that will address the questions which need answers before the next PM review cycle is completed. We understand that your staff is preparing a PM research plan for our review later this summer. We look forward to providing our comments on this important matter.

CASAC recognizes that your statutory responsibility to set standards requires public health policy judgments in addition to determinations of a strictly scientific nature. While the Panel is willing to advise you further on the PM standard, we see no need, in view of the already extensive comments provided, to review any proposed PM standards prior to their publication in the Federal Register. In this instance, the public comment period will provide sufficient opportunity for the Panel to provide any additional comment or review that may be necessary.

Thank you for the opportunity to present the Panel's views on this important public health issue. We look forward to your response to the advice contained in this letter.

Sincerely,



Dr. George T. Wolff, Chair
Clean Air Scientific Advisory Committee

TABLE I
Summary of CASAC Panel Members Recommendations
 (all units $\mu\text{g}/\text{m}^3$)

		PM _{2.5} 24-hr	PM _{2.5} Annual	PM ₁₀ 24-hr	PM ₁₀ Annual
Current NAAQS		N/A	N/A	150	50
EPA Staff Recommendation		18 - 65	12.5 - 20	150 ^{1,3}	40 - 50
Name	Discipline				
Ayres	M.D.	yes ²	yes ²	150	50
Hopke	Atmos. Sci.	20 - 50 ³	20 - 30	no	40 - 50 ⁴
Jacobson	Plant Biologist	yes ²	yes ²	150	50
Koutrakis	Atmos. Sci.	yes ^{2,5,6}	yes ^{2,5,6}	no	yes ⁴
Larntz	Statistician	no	25-30 ⁷	nc	yes ²
Legge	Plant Biologist	≥ 75	no	150	40 - 50
Lippmann	Health Expert	20 - 50 ³	15 - 20	no	40 - 50
Mauderly	Toxicologist	50	20	150	50
McClellan	Toxicologist	no ⁵	no ⁵	150	50
Menzel	Toxicologist	no	no	150	50
Middletton	Atmos. Sci.	yes ^{2,3,12}	yes ^{2,5}	150 ^{3,13}	50
Pierson	Atmos. Sci.	yes ^{2,9}	yes ^{2,9}	yes ⁴	yes ⁴
Price	Atmos. Sci./ State Official	yes ^{3,10}	yes ¹⁰	no ^{3,4}	yes ⁴
Shy	Epidemiologist	20 - 30	15 - 20	no	50
Samet ¹	Epidemiologist	yes ^{2,11}	no	150	yes ²
Seigneur	Atmos. Sci.	yes ^{3,5}	no	150 ¹³	50
Speizer ¹	Epidemiologist	20 - 50	no	no	40 - 50
Stolwijk	Epidemiologist	75 ⁷	25-30 ⁷	150	50
Utell	M.D.	≥ 65	no	150	50
White	Atmos. Sci.	no	20	150	50
Wolff	Atmos. Sci.	≥ 75 ^{3,7}	no	150 ³	50

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM_{10-2.5} standard rather than a PM₁₀ standard

⁵ concerned upper range is too low based on national PM_{2.5}/PM₁₀ ratio

⁶ leans towards high end of Staff recommended range

⁷ desires equivalent stringency as present PM₁₀ standards

- ⁸ if EPA decides a $PM_{2.5}$ NAAQS is required, the 24-hr. and annual standards should be 75 and 25 $\mu\text{g}/\text{m}^3$, respectively with a robust form
- ⁹ yes, but decision not based on epidemiological studies
- ¹⁰ low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have $PM_{2.5}$ pollution problems
- ¹¹ only if EPA has confidence that reducing $PM_{2.5}$ will indeed reduce the components of particles responsible for their adverse effects
- ¹² concerned lower end of range is too close to background
- ¹³ the annual standard may be sufficient; 24-hr level recommended if 24-hour standard retained

Senator INHOFE. Thank you, Senator Lieberman.

Senator HUTCHINSON.

Senator HUTCHINSON. Thank you, Mr. Chairman. I feel like I am getting a crash course in something that is way over my head.

As a layman listening to this, let me restate the issue and you tell me if it is a fair characterization. That there is no doubt that there was a lot of uncertainty and a lot of diversity of opinion. Both of you agree that it would have been nice to have more time and more studies. More information would be very helpful in determining definitively the causality issue. Your differences are that Dr. Lippmann would say that we should have the more stringent standard now and do the studies and Dr. Wolff would say that until we know and have more information and can do those studies we should hold off on the most stringent standard?

Is that a fair characterization of what I have heard?

Dr. LIPPMANN. With one exception. It is a very fair statement, but I would like to put in the other consideration that we don't have to wait now. A decision is called for at this point in time with the information we now have. We both agree that it is less fully convincing than we would like, but a judgment must be made now according to the Clean Air Act. But we both agree—and I think we are very close on the issues which are uncertain—on the kinds of uncertainties there are. We have worked very closely together on identifying the research issues. I think we see eye to eye on most of those.

Senator HUTCHINSON. While a decision has to be reached, it doesn't have to be this decision, the one that has been recommended.

Dr. LIPPMANN. No.

Senator HUTCHINSON. Dr. Wolff, would you respond?

Dr. WOLFF. I think you characterized it accurately. I think that there was a spectrum of opinions on the committee—

Senator HUTCHINSON. Dr. Wolff, the diversity of opinion that you alluded to—I think you said that four members supported the level near the low end of the EPA range, eight members declined to offer an opinion, seven members supported ranges at or above the EPA range, and two members did not think a 2.5 standard was needed. Is that accurate?

Dr. WOLFF. That sounds accurate.

Senator HUTCHINSON. That is on the PM. On the ozone there was a similar spread in diversity of opinion in that three members supported .08 PPM with multiple exceedances and three members supported .09 PPM with multiple exceedances and so forth. There was a big diversity.

Let me give you a series of questions so that I can let you expand.

Elaborate on the difference of opinion among CASAC. Why was there so much diversity? Considering that diversity, how did EPA come up with the PM_{2.5} standard in the first place?

Elaborate on the ozone area and diversity of opinions. Why was there so much diversity. How did EPA come up with a standard that was the most stringent of all the opinions expressed? And did EPA give CASAC any guidance as far as range of the standards?

Dr. Wolff.

Dr. WOLFF. Let me start at the last question first, Did they give us any guidance? The answer is yes. They suggested a range in their staff paper.

The diversity of opinion concerning the PM was real. There were recommendations all over the place. The reason for that diversity was mainly because of all the unanswered questions that popped up during the review, the many uncertainties. They ranged from a simple thing of saying that EPA has not adequately demonstrated that PM_{2.5} is the culprit. Maybe it is PM and maybe it is something else, perhaps a constituent of the PM. Maybe it is air pollution because most pollutant concentrations are correlated. But then you get two other people raising the fact that there is no plausible biological mechanism.

There were concerns that the monitoring—most of these studies were done using a single monitor outdoors to represent the exposure of all the people in that community. People raised the point that 90 percent of the time people spend indoors, so how could an outdoor monitor be representative of exposure over the whole community.

They go on from there coming to the biggest doubt that Senator Sessions brought up. There are studies that throw in humidity and the effect goes away. That is why there was a diversity of opinion.

Senator HUTCHINSON. Is it fair to say that there is one thing that can be agreed upon, that there are still an awful lot of unanswered questions. A great deal of information and scientific data needs to be gathered before there can be a definitive cosmology and—

Dr. WOLFF. Absolutely. We agree on that totally. Like Dr. Lippmann said, we have reviewed the Agency's research plans and made suggestions. We think we know what needs to be targeted in the next 5 years so that we don't go through this again in 5 years.

Concerning the ozone, the conclusion was that there was no bright line. We had agreement on that. But having said that, then some of the members wanted to give their personal preference. I didn't. I said it was strictly a policy call because I didn't think that a personal preference was a scientific opinion. But the personal preferences—and you have quoted them correctly—if you took some sort of average of them, you would end up selecting .09 with multiple exceedances. In the Federal Register notice, EPA acknowledges that. Then they say, on the other hand, the environmental groups and others are pushing for a .07. So they picked the middle.

Senator HUTCHINSON. My time is up.

Thank you, Mr. Chairman.

Senator INHOFE. Thank you, Senator Hutchinson.

Senator Allard.

Senator ALLARD. These scientific articles that you reviewed—I assume they were refereed and in your opinion the panel that refereed them were credible, highly respected scientists?

Dr. LIPPMANN. These are journal articles, which are reviewed in the scientific process. That is traditional. Only peer-reviewed journal articles came forward into the docket that we were looking at.

Senator ALLARD. But when you look at the scientific articles, some of these review panels are more tightly scrutinized than others, particularly if you are looking at an article, for example, that was written—the American Medical Journal is a very strictly ref-

ereed journal. On the other hand, the journal that may have been written for general circulation may not have had heavy scrutiny.

Dr. LIPPMANN. We are only talking about scientific manuscripts. We are not talking about general literature.

Senator ALLARD. I know, but I want to be clear on the committee is that both of you were comfortable that this was good scientific information in these journals and that what you're telling this committee is that these written articles—scientific articles—have been generally recognized by the science community as good science.

Dr. LIPPMANN. This was the best available science.

Senator ALLARD. In the studies that came forward—and we were looking at our standard. The average individual sitting in this room—would these changes in standards proposed here affect the normal person?

Dr. LIPPMANN. In all these air standards for all the years they have been setting them, following the Act, the focus has been on identifying a sensitive segment of the population and trying to see if it is a sizable segment, not a single individual or a few individuals. Asthmatics as a group is a segment which is relevant in this case.

I am healthy and when the ozone is above the current standard, I don't feel bad and perhaps you don't feel bad, but there is a sizable number of people—even if a small percentage—who is adversely affected.

Senator ALLARD. So your response is that a normal person would not notice the change in recommended standards?

Dr. LIPPMANN. Most people would not notice the change or have any impact on their health, but the sensitive segment of the population is responsive.

Senator ALLARD. You talked about an asthmatic. Is it 10 percent loss of function, 50 percent loss of function, 25 percent loss of function? When does that individual begin to notice a difference on these changes?

Dr. LIPPMANN. The sensory response is not directly related to the functional response. In healthy people, you get the functional response—

Senator ALLARD. Sensory?

Dr. LIPPMANN. Do you feel it? Or is it measurable? In other words, if I do a respiratory test on you, you may have less lung capacity, but you don't feel like you have less lung capacity because of your reserve.

But in our studies of the asthmatic children, the changes in lung function are there as they are in healthy children, but in asthmatic children they feel it. They get symptoms. They require extra medication when the ozone is high. The Connecticut River Valley is where we did our most recent study, in an area where you send children because it is clean. When the ozone was even below the current standards, the symptom rate of the children went up, they went to the health clinic and asked the physician for more medication.

We know that is good medical data because the physician had to agree that the child not only continued on that baseline medication but asked for extra medication on that day and it was given to them. We have an exposure response relationship for that effect.

Senator ALLARD. So that on a particular day when the ozone level was observed going up in your particular example, what was going on that day that caused the ozone to go up?

Dr. LIPPMANN. This is a regional phenomenon. The weather pattern sets it up, the high pressure areas—Dr. Wolff, who has meteorological background can give you a better technical definition. It is a random thing that happens a number of times each summer. You get these air masses which cook and develop ozone and the associated organic particles that form with the ozone.

Senator ALLARD. So there could be other factors involved rather than just ozone?

Dr. LIPPMANN. Yes. In fact, our study showed that the fine sulfate particles are also indicative of the response of these children.

Senator ALLARD. Part of the problem of having a bright line with ozone, for example, is not only the effect on a normal individual, but the diseased individual with various degrees of disease—maybe 30 percent loss of function as opposed to 10 percent.

Dr. LIPPMANN. A 30 percent loss of function wouldn't disable you or me, but for an asthmatic child who has less capacity, that is a big difference. That is why it is important to do these together because the ozone formation process leads to hydroxylions, which oxidize the SO_2 and make acidic fine particles. So you get the organic particles and the acidic particles because these things are in the air together. The decision by EPA to deal with both pollutants at the same time is a very good choice.

Senator ALLARD. With your tolerance and that of the committee, I would like to ask just one more question.

In some parts of the country, we have some background information that says that particularly in the western parts of the United States that the ozone level naturally may occur at .075. Would you agree with that?

Dr. LIPPMANN. No.

Senator ALLARD. It is an EPA staff paper on ozone, EPA 452/R-96-007, page 20.

Dr. LIPPMANN. I can't say it never happened, but that would be an unusually high background level. Dr. Wolff I am sure would agree.

Dr. WOLFF. Background is normally around .04. But there is considerable variability. In a given year, it wouldn't be unlikely to see that as high as .07 on a given day.

Senator ALLARD. So if we have a normal background that could occur at .075, in those parts of the country, how do you enforce that?

Dr. LIPPMANN. First off, as I said earlier, it is going to a multiple exceedance basis. So that rare day won't by itself cause an exceedance.

Senator ALLARD. Thank you.

Senator INHOFE. Thank you, Senator Allard.

Senator Graham.

Senator GRAHAM. Thank you, Mr. Chairman.

I would like to ask a few questions that relate to the process by which this very significant decision has been made. There are obviously important consequences of your scientific judgment which include economic consequences and consequences on public health.

Could you evaluate the degree of exactness, certainty of the science, that undergirded this review of ozone and particulates in comparison to other scientific issues that have come before CASAC and their degree of precision and exactitude?

Dr. WOLFF. I think the ozone review was done in a manner that was similar to the past reviews in that we were able to come to a consensus. I think that is the key. If you can come to a consensus, then the level of comfort with the science is pretty adequate. We were able to do that with ozone even though we concluded that there was no bright line, but that was the best science could do. I don't think that we can push the science at this point much further.

For the PM, I think there was a high level of discomfort, not with the quality of the science, but because there were different interpretations of the science that led to the diversity of opinion and no consensus on the committee.

Dr. LIPPMANN. This is not a unique kind of review in sharing the previous rounds of reviews for the criteria pollutants. The process, if anything, improved. The number and quality of the available information has improved. It is comparable to my experience on other SAB activities. I chaired the environmental tobacco smoke review, the risk assessment. I am currently chairing the dioxin risk assessment review. These are very difficult issues where no manufacturer is coming in and asking for an approval and having to submit the proof that their product is safe. This is information generated for other purposes and interpreted as necessary to make these decisions.

What makes these decisions different is the implications that are involved. We hadn't previously come down to levels approaching background. So there is another level of complication in this review, which leads to the personal preferences being different, recognizing the implications.

In the past, we were dealing with ranges and levels where there was somewhat discomfort or lack of it on the public interest side and the industry side because it would be expensive. Now we are getting down to levels of concern that may not even be feasible in the short run and only gradually approached. So I think that is where the difference is, not in the process, but in the implications and how that fed back into the way individual committee members reacted.

Senator GRAHAM. But in spite of that schism you just described, there was a consensus within the committee on the recommendation that went to the Administrator. Is that correct?

Dr. LIPPMANN. Yes. We did endorse the ranges put forward by the staff paper as a consensus of the committee for both.

Dr. WOLFF. No, we didn't endorse the range for PM.

Dr. LIPPMANN. Yes, we did.

Dr. WOLFF. No, we didn't. There were members whose recommendations—

Dr. LIPPMANN. The personal preferences were different, but they endorsed the range.

Dr. WOLFF. No, they didn't.

Dr. LIPPMANN. Well, we disagree.

[Laughter.]

Senator GRAHAM. Let's ask each to state precisely what your understanding of what was or not agreed to.

Dr. WOLFF. The range for the 24-hour PM_{2.5} value that EPA proposed was 18 to 65 micrograms per cubic meter. There were a number of members who recommended that it be 75 micrograms per cubic meter. There were a number of members who recommended that there not be a 24-hour standard. So I can't say that there was consensus on the range because there were a number of members who either favored something higher or didn't favor it at all.

Senator GRAHAM. What number of the members of the committee approved the EPA's 18 to 65 range?

Dr. WOLFF. There is a table in the—in fact, we have a table here but I don't know if you can see it. It is also a table in my written comments. It is on page 7 of the written material. The first column is the recommendation for the 24-hour standard. The range that EPA expressed was 18 to 65. You can see that as you go down, there are four people that prefer a range that is within the range of EPA's, then a number of yeses that simply say that they endorse a 2.5 standard but decline to select a range. So we can't say positively one way or the other whether they endorse the range or not. Then as we go down, we get into some noes, one greater than or equal to 65, some 75's. It looks to me that of the members who made a commitment, the majority of those favored something that was above the range or a simple no.

Senator GRAHAM. Dr. Lippmann, what is your interpretation?

Dr. LIPPMANN. I interpret all the yeses to be an endorsement of the range. There is no question in my mind about that.

Dr. WOLFF. The "yes" is not an endorsement of the range. I was the one who collected the comments.

Senator INHOFE. Thank you very much.

Seeing that there are no further questions, I want to thank the first panel very much for coming. Since we went a little over our time, we won't have a second round of questioning. If there are any further questions of members of the panel or committee, we would like to submit them in writing and would ask you to respond to both the member who requested and the committee.

Thank you very much.

Senator INHOFE. I now ask that our second panel, our ozone panel, come to the witness table.

Our second panel is Dr. Daniel Menzel, Community and Environmental Medicine, University of California, Irvine; Dr. George Thurston, associate professor, Department of Environmental Medicine, New York University School of Medicine; and Dr. Roger O. McClellan, president, Chemical Industry Institute of Toxicology.

You heard the instructions to the previous panel. If you can adhere to the 5-minute comments, your entire statement will be submitted, without objection, into the record.

We will first hear from Dr. Thurston.

**STATEMENT OF GEORGE THURSTON, ASSOCIATE PROFESSOR,
DEPARTMENT OF ENVIRONMENTAL MEDICINE, NEW YORK
UNIVERSITY SCHOOL OF MEDICINE**

Dr. THURSTON. Thank you.

The adverse health consequences of breathing ozone at levels below the current U.S. national ambient air quality standard of 120 parts per billion ppb are serious and well documented. This documentation includes impacts demonstrated in controlled chamber exposures of humans and animals, and observational epidemiology showing consistent associations between ozone and adverse impacts across a wide range of human health outcomes.

Observational epidemiology studies have shown compelling and consistent evidence of adverse effects by ozone below the current United States standard including decreased lung function, more frequent asthma symptoms, increased numbers of asthma attacks, more frequent emergency department visits, additional hospital admissions, and increased numbers of daily deaths.

In my own research, I have found that ozone air pollution is associated with increased numbers of respiratory hospital admissions in New York City, Buffalo, New York, and Toronto, Ontario, even at levels below the current standard of 120 ppb. My ozone-hospital admissions results have been confirmed by other researchers considering other locales.

The United States EPA used my New York City asthma results in the staff paper—and I guess we will be hearing more about them—when estimating the health benefits of lowering the ozone standard. However, they failed to consider other respiratory admissions affected, such as for pneumonia or bronchitis. Thus, considering the published results from various cities, the EPA analysis under-predicts the respiratory hospital admission benefits of their proposed regulations by about a factor of two.

This month, the results of a study I conducted on the effects of air pollution on children at a summer asthma camp in Connecticut will be published. This study of a group of about 50 moderate to severely asthmatic children shows that these children experience diminished lung function, increased asthma symptoms, and increased use of unscheduled asthma medications as ozone pollution levels rise. On the highest ozone days, the risk of a child having an asthma attack was found to be approximately 40 percent greater than on an average study day, with these adverse effects extending to below 120 ppb ozone.

I might add that this is right near the border of Rhode Island. I am sure that this same pollution adversely affected children in Rhode Island, my home State.

More recently, I have found that daily mortality also rises after high ozone days in the U.S. cities of New York City, Atlanta, Detroit, Chicago, St. Louis, Minneapolis, San Francisco, Los Angeles, and Houston, and at ozone levels reaching below the current standard. While not yet published, these U.S. results are supported by previously published results, and by a recent spate of new papers by other researchers showing similar associations between ozone and human mortality around the globe, including a recent study of mortality in London published in the British Medical Journal.

It is important to keep in mind that the above described epidemiology is supported by a large body of knowledge from controlled exposure studies that give consistent and/or supportive results, and that have demonstrated pathways by which ozone can damage the human body when it is breathed. Clinical studies have dem-

onstrated decreases in lung function, increased frequencies of respiratory symptoms, heightened airway responsiveness, and cellular and biochemical evidence of lung inflammation in health exercising adults exposed to ozone concentrations as low as 80 parts per billion for 6.6 hours. Now, clearly, the EPA proposal is based on sound science.

Airway inflammation is especially a problem for children and adults with asthma, as it makes them more susceptible to having asthma attacks. For example, recent controlled human studies have shown that prior exposure to ozone enhances the reactivity of asthmatics to aeroallergens, such as pollens, which can trigger asthma attacks.

In addition, increased inflammation in the lungs can make the elderly more susceptible to pneumonia, a major cause of illness and death in this age group.

The EPA has proposed a standard of 80 ppb averaged over an 8-hour period, rather than the existing 120 limit for the highest hour of each day. The switch to an 8-hour average is clearly appropriate, based on the scientific evidence that the cumulative effects of multiple hours of exposure are worse for people than a single peak hour of exposure.

However, since significant adverse effects are well documented down to the 80 ppb level, the EPA proposal provides no margin of safety. This is especially true since the proposed law will allow several exceedances of this level before a violation is cited. Thus, the health evidence would indicate that a standard set at 70 ppb ozone averaged over an 8-hour period is needed, if any margin of safety is to be provided to the public, rather than the 80 recommended by the EPA.

It is interesting to note what levels other deliberative bodies have recommended regarding permissible ozone levels. In Canada, the daily 1-hour maximum allowed is 80 ppb of ozone, which is roughly equivalent to an 8-hour limit of about 60 ppb ozone. In addition, the World Health Organization similarly recommended an 8-hour average guideline of 60 ppb for ozone over 8 hours. Also, recently the American Conference of Governmental Industrial Hygienists have proposed lowering the TLV for ozone to 50 ppb over an 8-hour work day for workers under heavy exertion. This would indicate that healthy American workers need to be protected from levels that would be perfectly legal for the rest of us to breathe under the USEPA's proposals. The EPA's new proposed ozone limit is weak when compared to standards set or recommended by others.

In conclusion, I would like to reiterate the key messages contained in the letter that I and 26 other air pollution researchers and physicians sent to President Clinton last month. Please listen to the mainstream medical and scientific community on this issue. Exposures to ozone and PM air pollution have been linked to medically significant adverse health effects. The current standards for these pollutants are not sufficiently protective of public health.

Thank you for the opportunity to speak to you.

Senator INHOFE. Thank you, Dr. Thurston.

Dr. Menzel.

STATEMENT OF DANIEL MENZEL, COMMUNITY AND ENVIRONMENTAL MEDICINE, UNIVERSITY OF CALIFORNIA, IRVINE

Dr. MENZEL. Thank you very much, Mr. Chairman.

My name is Dan Menzel. I am professor and chair of the Department of Community and Environmental Medicine, University of California at Irvine. I have submitted a written statement for the record and I will just summarize some important points that I believe are of interest to the committee.

The committee has asked that I provide my views on the ozone standard, and I am pleased to do that. I would also like to extend my testimony to include the research effort of EPA because it directly affects the standard-setting process. In my written testimony I have also stated my views on particulate matter standards and research agenda because the two standards are interrelated. Particulate matter may be a surrogate for the complex mixture of air pollution, including ozone.

The ozone standard is in need of revision, despite a continuing lack of information. Recent human controlled exposure studies have shown that some individuals have a decrement in respiratory function on inhalation of ozone at the current national ambient air quality standard of 120 (ppb). Some studies have also shown that changes occur in the pulmonary, immune, and defense systems. Recently one of my colleagues has shown that ozone-induced changes in cell permeability occurs in rats at ozone concentrations near the current standard.

A very large number of experimental animal studies have shown that the magnitude of the exposure to ozone—that is, the amount of ozone—is more important than the duration of exposure in the chronic effects of ozone. Both the human exposure pattern and experimental animal studies show that chronic exposure to ozone is the most important for adverse health effects.

Despite much work, the risks associated with different exposures to ozone are not well known. Much work remains. The ozone story is not a closed book.

The ozone standard should have a shorter averaging time to reduce the number of times people are exposed to high peaks of ozone. I favor the 8-hour averaging time. We do not have good data on how much the risk of lung disease will be reduced by reducing the standard from 120 to 90 ppb. In fact, you heard a comment that the current standard really is closer to 90 ppb if the 8-hour averaging time is implemented.

It may be that a much greater reduction in the ozone standard will be needed in the future. The standard should therefore remain at 120 ppb with an 8-hour averaging time and let us see whether the ozone standard can be attained with a shorter averaging time and what exactly will happen.

Since the chairman has not heard a request for additional money, I thought I would raise this issue and suggest that EPA should join with its sister agencies, NIH and NSF, and mount an integrated research program. It seems to me that the program should develop a comprehensive study for the chronic effects of air pollution. Such a program will point out the biological mechanism on an integral level. This is again back to the plausible biological mechanism as the basis for all studies that we should do.

We should define the dose-response as responsible a relationship as precisely as possible. We should seek biochemical markers of ozone toxicity in humans for use in molecular epidemiology studies. We need to improve the extrapolation model of ozone so that a precise estimate of the ozone dose can be made for humans in controlled exposures, experimental animals, and actual human exposures. We need to enhance the risk assessment.

I would like to discuss a few generic problems that I see with EPA's research agenda that are leading to these uncertainties in the standard-setting process.

EPA's research program in the health effects of air pollution has suffered so much reduction in funding that it should be no surprise that there are major data deficiencies at the time of the standard setting. EPA has responded to the lack of resources for long-term research by a crisis approach to solving long-term problems. Judgments are being made on incomplete data and public confidence, in my view, is being eroded.

National programs can solve major problems. We have seen this in the AIDS research program. It is a remarkable success. Government and scientists have to resist the temptation to tire of difficult, long-term problems. We scientists must insist that air pollution research deserves the highest priority nationally in health research, something we haven't done in the past.

Congress, in my opinion, can help resolve the continuing conflict over air pollution health effects by directing and empowering through appropriations enough resources so that EPA, NIH, and NSF can mount an integrated national program. In my view, surely the economic impact of air pollution alone is enough to justify such a national program.

Thank you.

Senator INHOFE. Thank you, Dr. Menzel.

Dr. McClellan.

**STATEMENT OF ROGER O. McCLELLAN, PRESIDENT,
CHEMICAL INDUSTRY INSTITUTE OF TOXICOLOGY**

Dr. McCLELLAN. Mr. Chairman and distinguished members of the subcommittee, I am pleased to have this opportunity to testify at your request on the scientific issues related to the proposed new standards. I request that my written testimony be included in the record.

Senator INHOFE. Without objection, your prepared statement will appear in the record.

Dr. McCLELLAN. By way of background, I serve as president of the Chemical Industry Institute of Toxicology, a not-for-profit research organization located in Research Triangle Park, NC. The mission of that organization is to develop an improved understanding and scientific basis for assessing the human health risks of exposure to chemicals.

The comments I offer today are based on my experience as a scientist concerned with the risks of airborne materials and my extensive service in advisory roles to numerous public and private advisory public organizations that has included service on EPA's Science Advisory Board, including service under each of the EPA's administrators on a number of committees, including serving as

chair of the Clean Air Scientific Advisory Committee from 1988 to 1992.

Based on the conversation in the last round, let me digress from my written comments and give a little perspective.

The Clean Air Scientific Advisory Committee reviewed the scientific basis for the NAAQS for PM for an extended period of time, from 1979 to 1986, before the PM₁₀ standard was promulgated in 1987. During the 1980's we had a continuing review of the basis for the ozone standard. In fact, we had a criteria document prepared and then a supplement to the criteria document. Both of the PM and ozone reviews were characterized by an iterative pattern of collection of data, synthesis, review, identifying research gaps, research, and review again. Finally, over a 7-year period we came to a closure, yet with a high degree of uncertainty as to the adequacy of the PM data for making a regulatory decision. That was the basis of promulgating the PM standard in 1987.

In the case of ozone, we came to a different conclusion. There was a divergence of scientific opinion in 1989. We related that to the Administrator. Administrator Reilly ultimately reaffirmed the existing standard and initiated the current process that we are just coming to closure on for ozone. Now, we have come together. The degree of uncertainty in the ozone picture today, is much less than it was in the late 1980's. As a result, I think there was a very strong consensus on CASAC. We have quite a different situation with regard to PM.

Let me say that there was new scientific information that came to bear during the last decade on ozone. This information was appropriately reviewed by the EPA in their criteria document, reviewed by the staff in their position paper, and I think it allowed us to come to a strong consensus that ozone was the appropriate indicator in terms of photochemical oxidants. It was also appropriate to move to an 8-hour averaging time from the 1-hour averaging time. But I hasten to add that the 8-hour and 1-hour are relatively closely correlated so that even though we didn't have an 8-hour standard in the past, we were on the right track. We are on an even better track now as we shift to an 8-hour standard.

We already heard that CASAC had a consensus that there was no threshold for ozone, no bright line between adversity and a lack of adversity. Based on that, the EPA staff suggested a range for an 8-hour averaging time of 0.07 to 0.09 PPM ozone. The committee members came down within that range. I personally favored a 0.09 PPM standard with an 8-hour averaging time and the use of a 3-year average of the annual third highest maximum 8-hour average.

My professional opinion was heavily shaped by information such as shown in this chart. I would say that the basis of the chart is drawn from an excellent piece of work carried out by Professor Thurston of NYU, who studied hospital admissions in the New York City area and the relationship to ozone levels.

I would call your attention to the top line. This is simply estimated hospital admissions related to asthmatics in the New York area. You will see excess admissions for the different forms of the standard levels from 0.12 down to 0.07 and differing averaging types.

I call your attention to the fact that these are remarkably similar. There are numbers that range from 60 to 240 as contrasted to the "as is" of 385. Dropping down to the second row the values are expressed on a percentage basis. The numbers are relatively large; for example, plus 83 percent in terms of the present "as is", which suggests that we will be reducing that as we go to various standards there.

It is important to look at the third row where we have that excess plus the background. This is key because the EPA is using a linear model in the background that contributes 680 cases, more than any of the elevated levels. This ozone background is practically impossible to address. So when you look at it then as a percentage change compared to the present standard, we see very much smaller numbers.

What I think is very important from a policy standpoint is the issue of all asthma admissions. We see these are something on the order of 28,000 plus cases. Now when we look at what different standards do in terms of the asthma cases, we see very small differences.

To me, this is the kind of risk analysis that points to the fact that the ozone standard-setting is really a policy call as to which standard you select from the array of possibilities. That is the analysis that shaped my opinion on the ozone standard.

Before closing, let me comment briefly on the PM standard. I was one of the two individuals on the CASAC who did not endorse a PM_{2.5} standard. My position is that we do not have sufficient information today. It is important that we understand the nature of this standard. Attached to my testimony is a simple graph which shows you that on the horizontal dimension we have the size cuts, if you will. On the vertical, you will see the level or quantity. My viewpoint is that we do not have enough information on the size characteristics of material in the air, and we may be very likely setting an inappropriate standard that will not yield health benefits.

Senator INHOFE. Thank you, Dr. McClellan.

I will start the questions. I think I will do it differently this time and start with one individual and just concentrate on one at a time.

Dr. Menzel, a lot has been discussed and a lot of emotion has been stirred up by the media and the fact that ozone causes decreased lung function, with the greatest percentages being a decrease of 20 percent in lung capacity.

Are these cases permanent?

Dr. MENZEL. It is very difficult to say on an individual basis whether they are permanent or not. On the other hand, a lot of my research has dealt with the question of how permanent things would be on a continuous exposure or intermittent exposure that would mimic human effects. In those cases, in experimental animals where we can see the life term effects, it is a permanent, irreversible change.

Senator INHOFE. If you are experiencing a 20 percent decrease in lung function, do you always know it?

Dr. MENZEL. No. As was mentioned by Dr. Lippmann, it is very difficult for us to feel changes, unless we are at the later stage in life or if we have a preexisting disease such as emphysema, bron-

chitis, or asthma where we have a major decrease in lung function to begin with. Then when we are down at that low level, any incremental decrease would be appreciated in the way people can carry out their lives.

Senator INHOFE. So there are many causes of this condition?

Dr. MENZEL. Yes, that is the whole problem. It is the plausible biological explanation. In the case of ozone, we have one for short-term effects. I was the guy who suggested it, but I don't believe that my theory, free radical reactions, actually applies to the long-term chronic effect.

Senator INHOFE. Is there a level of ozone where there would be no decreased lung function?

Dr. MENZEL. It is very difficult to say yes or no to that question, and I don't mean to equivocate. Obviously I am critical of existing programs, so I am not afraid to say what I think, but the basic problem is that the shape of the ozone response relationship is so uncertain that we really cannot come to a conclusion. A conservative estimate would be a linear dose response saying that at any concentration of ozone there is some change. But I don't know whether we can say that with any certainty.

Senator INHOFE. Dr. Thurston, in your Canadian studies that you published in May 1994, you state that the ozone is responsible for 21 percent of the hospital admissions for respiratory complaints.

Dr. THURSTON. During that period, that sounds roughly correct.

Senator INHOFE. You asserted that the study showed an increase in hospital admissions during the months of July and August for 1986, 1987, and 1988 when the ozone exceeded the Canadian ozone standard of 0.08 at that time.

Could there have been other factors that contributed to these admissions, such as heat and humidity?

Dr. THURSTON. Heat and humidity is not a big problem in Toronto. It is much cooler there, right on the lake. We did, however, consider that in the model. For that matter, when you look at asthma, it is cold temperatures that are important to asthmatics. When you have cold temperatures, that is when they react to temperature. Warmer temperatures would have to get well above what you see in Toronto to start having any adverse effects.

Senator INHOFE. Did you control for such things as other pollutants?

Dr. THURSTON. Yes, we did look at multiple pollutants. That is one of the advantages of that study.

Senator INHOFE. I was kind of surprised to find out that if you controlled for the wealth in your study—apparently there is a study that was done that says that for every \$10,000 decrease in median income it had tremendous effects on this, such as an 18 percent increase in premature death, 15 percent increase in cancer rate, 27 percent increase in lung cancer. It is kind of an interesting thing I hadn't thought of.

Did you control for that?

Dr. THURSTON. That is controlled for in the design. You see, each person—in this case, a population is their own control—we are following the same population over time. So whatever their status and wealth is, certainly, over the months we looked at them, it didn't change. What changed was the pollution levels. When the

pollution levels went up, we found that there was a bump in the admissions.

Dr. McClellan, one of the things I keep running into is that we have had significant reductions in ozone levels over the last 10 to 20 years, yet we have had significant increases in the incidences of asthma among children.

How would you react to that?

Dr. McCLELLAN. I think you have characterized it well, although I would say that our ozone levels have not gone down as much as we would like. But overall we have had very significant improvements in air quality, as you all related at the opening of the session.

Why we continue to see an increase in asthma is certainly unknown. It is a situation of personal interest to me in that one of my children is an asthmatic, yet having grown up in the clean air of New Mexico. I know the wide variety of circumstances that will trigger an asthma attack for him.

I think one of our major issues in terms of respiratory disease and health today is that we simply do not know what causes asthma. We have some interesting speculation and hypotheses in terms of issues of indoor air quality. There have been suggestions recently related to past immunization practices and how they may influence what is going on with regard to asthma.

The actual fact is that I don't think anybody today has been able to put forth a convincing basis for why asthma continues to go up, but I certainly think that the basis of asthma in terms of air pollution simply isn't there. The issue of air pollution and air quality triggering asthma attacks is a secondary issue.

Dr. THURSTON. Could I comment on that?

Senator INHOFE. Certainly.

Dr. THURSTON. Yes, I basically agree. That study that was mentioned states what we understand now. It does not appear that air pollution is causing this epidemic in asthma. However, as the number of people who have asthma rises, more and more people are there who are especially susceptible to air pollution because of asthma. So while air pollution doesn't appear to cause new cases of asthma, once people have asthma, then air pollution does aggravate their asthma. As I mentioned earlier, exposure to ozone increases asthmatics reactivity to things they would normally be reactive to, like pollen. A physician might see someone come in and do a skin test and determine that they had reacted to pollen. They are unaware that perhaps yesterday, they were exposed to ozone, which increased their sensitivity. That is why they reacted that day, as opposed to another day.

Senator INHOFE. Dr. McClellan, I have one last question.

Even though this is an ozone panel, you have expertise in both PM and ozone. If you were to remove all the pollutants covered by this regulation, would you resolve the asthma problem?

Dr. McCLELLAN. No.

Senator INHOFE. Senator Sessions.

Senator SESSIONS. Dr. Thurston, would New York be one of the better monitored cities as far as ozone level in the atmosphere?

Dr. THURSTON. It could be monitored better. It has a couple of stations in the city.

Senator SESSIONS. Is that an adequate number of stations for a city like New York?

Dr. THURSTON. Ozone happens to be one of the pollutants that happens to be widespread. One station is a pretty good indicator of levels. Certainly if you know the levels are high at one station, they are going to be high at another station, and low with low.

Senator SESSIONS. There doesn't seem to be a lot of divergence across town?

Dr. THURSTON. There is variability spatially within a city, depending on what local sources are there and things like that. So there is some, but they are highly correlated with one another. The absolute levels may differ somewhat. You may get an exceedance in one spot and be slightly below the standard in another. But a high day is a high day across the city, and a low day is a low day across the city.

Senator SESSIONS. With regard to your study of asthmatics in New York with hospital admissions, do you agree with Dr. McClellan that for policymakers the last line there is the best numbers to use for an evaluation of the effect of ozone?

Dr. THURSTON. I am not sure I understand the question exactly.

Senator SESSIONS. There are various numbers, like on line two, which are fairly dramatic. Line six shows modest variations, at best, as to the ozone level.

Dr. THURSTON. I think that is really an indication that the standard being proposed is not that much more stringent than the existing standard. It is changing the form somewhat and is going down 10 percent, but allowing more exceedances. So that would probably be a way you could show the least impact of pollution on people's health, if you want to look at it that way.

Senator SESSIONS. But that would be the most accurate, would it not, as to ozone?

Dr. THURSTON. No. I think there are various ways to look at this. One of them is the point that if you look, for example, at New York or Rhode Island, where they are trying to improve the air, but they are in violation—with the new standards of 8-hour, they would be able to make quicker progress toward cleaner air because the air being advected into the State will be cleaner to start with because there will be more counties upwind that will be cleaned up. I think we as a Nation will be able to make faster progress on ozone air pollution and the benefit will be more widespread than this would indicate because more counties would be influenced with these new standards than under the existing standards.

Senator SESSIONS. It had the level in the analysis.

Dr. McClellan, do you think line six is the best analysis of the effect of ozone on asthmatic hospital admissions?

Dr. MCCLELLAN. I do. I think what is important for a policymaker like Administrator Browner is to focus on total asthma admissions, the total problem, and now looking at what she has responsibility for, the ozone standard—how does it really influence that? I think you look at total asthma admissions and you have to say that it is a policy call. The variation in values for different potential standards doesn't drive you to one of those columns as a standard that is clearly more protective of health. It isn't there in

that table. It is a policy call. You can't use this to say that you are driven to set the standard based on the health data.

Senator SESSIONS. Dr. Menzel, would you comment on that?

Dr. MENZEL. I agree with what Dr. McClellan has said. Perhaps I couched my language a little too academically in my statement, because that is basically what I was saying. If we try to make an estimate of the difference in the health risk for different ozone exposures, we are very uncertain because we don't know the nature of the risk relationship to ozone declines. Would it decline in the ozone concentration—it is very difficult to come to a finite number, or a bright line.

This discussion centering around asthma brings up the issue that I really was hoping that I could encourage you to think about. That is that air pollution, although it is a regulatory requirement of the Environmental Protection Agency, it is a national public health problem. Therefore, it needs to be attacked with a national kind of approach. The National Institutes of Health really ought to think more about air pollution. The National Science Foundation ought to think more about the chemistry of air pollution. It isn't EPA's problem. It is all of our's problem.

Senator SESSIONS. Along that line, you have expressed some concern about EPA. In your opinion, have they wisely used the resources they have available to them?

I understand, Mr. Chairman, that appropriations were only slightly less than requested last year for EPA.

Have they wisely used the resources they have to prepare for this day that they knew was coming?

Dr. MENZEL. Let me say that EPA is a grossly under-funded agency. If you look at what they have been mandated to do by the Environmental Protection Act, and then compare that with the appropriations they have been able to garner, it is just not enough money.

So what have they done? This is a management decision that other administrators have made over the years, which is to go from here to here to here to here, shifting resources depending on the deadline. I would submit to you that 5 years is really not a very adequate time to gather the information we need for either ozone or particulate matter. You are really looking at a 10-year research program.

Senator SESSIONS. Dr. McClellan, do you have any comments on that?

Dr. MCCLELLAN. I would say the answer to that question is that the scientific staff of EPA has done an admirable job with the resources they have been allocated. The problem is that the dollars allocated to research within the EPA are an inappropriate portion of the total budget. EPA cannot label itself as a science agency when it spends less than or approximately 10 percent of its budget on research.

Senator SESSIONS. That is all they spend on research?

Dr. MCCLELLAN. Yes, 90 percent of the dollars go to the promulgation of standards, their enforcement, and all the other activities. But all of those activities are built on a science base that only gets 10 percent of the pie. That is not enough.

So the problem is that we are still dealing with an Agency that is a collection of fiefdoms—air, water, toxics—and we need some leadership at the top that says we will have a science base underpinning all of this and at long last create the science that will lead to science-based standards.

Senator SESSIONS. Thank you very much.

It is my observation that agencies do become bureaucratic and fiefdom dominated and that periodically they need to break through that and ask themselves what their real mission is. Thank you all very much.

Thank you, Mr. Chairman.

Senator INHOFE. Thank you, Senator Sessions.

Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

Dr. McClellan, let me say first—I don't know that you meant to personalize this, and I understand the appeal for more funding for research because I support it—but it does seem to me in the years that Carol Browner has been the Administrator of EPA, particularly with regard to these proposed standards, that she and we together have tried very hard to be more science-based. Maybe we could spend more money on the research, but we have asked EPA to do an awful lot of things and they have made some research judgments. We could disagree with them, but I do think the whole tendency has been to focus it more on science.

Dr. McClellan. Let me say that I certainly would not like my remarks to be construed as relating only to Administrator Browner. I think the situation has been true from the very beginnings of the Agency. It is true whether we have had a Republican Administration or a Democratic Administration. We tend to take a linear view of the budget process and the budget allocation. I think we need to step back and really take a look at the bigger picture. That is going to require help from all of us, certainly the Congress, the Administrator, and the scientific community at large.

Senator LIEBERMAN. I appreciate that statement. There may be disagreement among the panel here and the one before about these proposed standards. There is agreement that we would only benefit from more investment in research, and the amounts of money, relatively speaking concerning the overall Agency budget let alone the alleged consequences of various of these proposals, is minimal.

Talking about ozone now, there was a consensus on CASAC that going from the .12 to .07 to .09 parts per million of ozone was an appropriate range. You said that you decided within that range, although you chose .09. Is that correct?

Dr. McClellan. That is correct. We have two things going here. One is the form of the standard going from a 1-hour averaging time to an 8-hour. The fact is, in general across the country 1-hour and 8-hour are quite closely correlated. As several speakers have noted, 120 part per billion 1-hour average is roughly the same as 90 part per billion 8-hour average. When I looked at it I think the committee was in total agreement on the appropriateness of moving toward the 8-hour average, as being more health-relevant. Then the EPA staff had proposed a range of 70 to 90. I was one of the individuals who said that 90 would be appropriate.

Senator LIEBERMAN. But the CASAC consensus was that the range of 70 to 90 was appropriate. Is that correct?

Dr. MCCLELLAN. In fact, in terms of the panel, one individual preferred a level of 90 to 100, three were at 90, one was at 80 to 90, three were at 80, two said it was a policy call, and no individuals on the panel elected to advocate the 70 part per billion.

Senator LIEBERMAN. Do I derive from that that a majority of those on the panel fell within the 70 to 90 range?

Dr. MCCLELLAN. Yes. We basically said that the science doesn't lead you to say one of these numbers more appropriate than the others. Basically we said that it was a policy call.

Senator LIEBERMAN. That is an important point. There was the 70 to 90 agreement as an appropriate range. In fact, Administrator Browner chose 80, which was a policy call. Obviously you disagree with it, but it was within the appropriate range. I guess that is the point I was trying to make. She didn't reach way outside the range.

Dr. MCCLELLAN. No, that is absolutely correct.

Senator LIEBERMAN. On the sensitive populations—and I do think it is important to clarify that we are talking about millions of people here. There are millions of people who have asthma. One of my kids has asthma. It is very real for them and for all of us who are in their families or who are their friends. But I do want to stress something that I think is very important.

Dr. Thurston made a point and I presume the two of you would agree. No one here is saying that ozone causes asthma. So the increase in asthma in our population—we don't quite understand it, but it is not from ozone. Is that right?

Dr. MCCLELLAN. That is correct.

Dr. THURSTON. We don't know what causes the development of asthma.

Dr. MCCLELLAN. The causal factor in the increase in asthma is simply unknown.

Senator LIEBERMAN. Maybe you're going to tell me that we don't know that it's not caused by this.

Dr. MENZEL. I have written several papers on a theory that I proposed that ozone is an underlying cause for pulmonary inflammation. Therefore, it is a baseline kind of cause of inflammation. So we don't really know what that means in terms of the incidents of asthma.

I would say that we also have to remember that there are not only people who are asthmatic. People who have emphysema and bronchitis and other kinds of interstitial fibrosis. These are all lung diseases.

Senator LIEBERMAN. You had a very powerful sentence in your prepared testimony, Dr. Menzel. Very compelling, controlled human exposure experiments suggest that the current ozone standard, which is the 120 ppb, may be toxic.

Dr. MENZEL. Yes, that's true. We may be faced with having to make major reductions. I think the question of changing the frequency may have greater impact than we think.

Senator LIEBERMAN. My point here—and I think most of you would agree—I think we are saying that ozone exacerbates asthma for some of those who have it. We are not saying that it causes asthma.

Mr. Chairman, I have one final question.

Dr. McClellan, am I right in reading that chart to say that the new standard proposed by the Administrator would result in between a 13 and 44 percent reduction in ozone-related admissions?

[The two referenced charts follow:]

TABLE 1: ESTIMATED HOSPITAL ADMISSIONS FOR ASTHMATICS IN THE NEW YORK CITY AREA FOR VARIOUS OZONE CONTROL SCENARIOS

Row	IH1EX*	IH1EX	8H1EX	8H1EX	8H1EX	8H1EX	8H5EX	8H5EX	AS IS
1	0.12	0.10	0.10	0.10	0.09	0.08	0.09	0.08	
2	Excess Admissions ^a	210	130	240	180	110	180	120	≅385d
3	% Δ from present standard	0%	-38%	+14%	-14%	-48%	-14%	-42%	+83%
4	Excess + background ^b	890	810	920	860	790	860	800	1065e
5	% Δ from present standard	0%	-9%	+3%	-3%	-11%	-3%	-10%	+20%
6	All Asthma Admissions ^c	28,295	28,215	28,325	28,265	28,195	28,265	28,205	28,470f
7	% Δ from present standard	0%	-0.3%	+0.1%	-0.1%	-0.4%	-0.1%	-0.3%	+0.6%

*IH1EX - 1 hour averaging time, 1 exceedance

a - excess asthma admissions attributed to ozone levels exceeding a background concentrations of 0.04 ppm; from Table VI-2, page 155 in the August 1995 OAQPS Draft Staff Paper

b - asthma admissions included in (a) plus those due to background ozone concentrations: admissions due to background = 1065e - 385d = 680

c - asthma admissions due to all causes = 28,470f - 385d + Excess Admissions from row 1

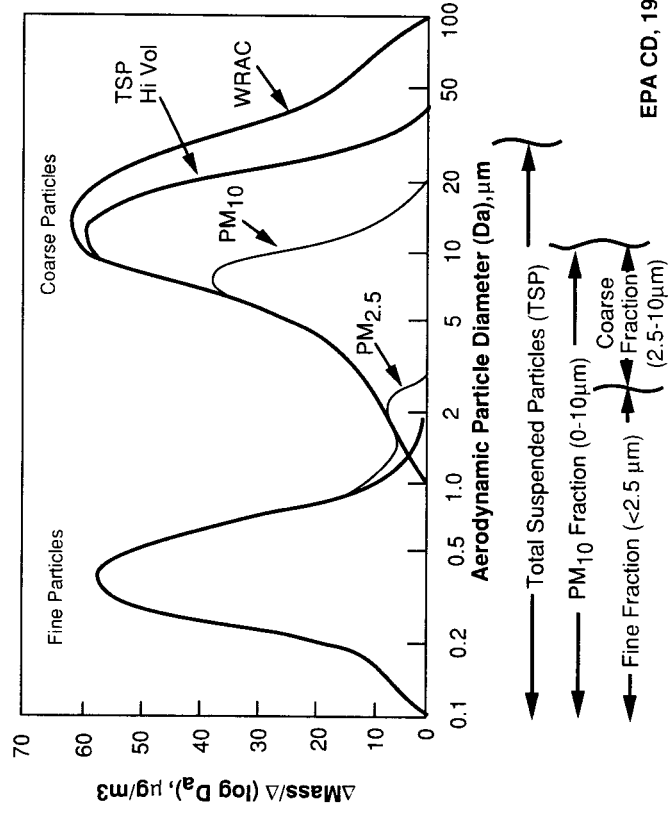
d - estimated from Figure V-15, page 125 in the August 1995 OAQPS Draft Staff Paper

e - from page 127, line 13 in the August 1995 OAQPS Draft Staff Paper

f - total admissions from asthma = total asthmatics (365,000) - from page 126, line 24) x hospitalization rate (78/1000 asthmatics - from page 126, line 29)

Adapted by the Clean Air Scientific Advisory Committee Ozone Panel from the EPA Ozone Staff Paper. The notations in the footnote above refer to the August 1995 OAQPS Draft Ozone Staff Paper.

**SAMPLING FRACTIONS FOR AN IDEALIZED
AMBIENT PARTICULATE MASS DISTRIBUTION**



EPA CD, 1995

Dr. MCCLELLAN. There is actually not a value on there that exactly corresponds to what she has proposed. EPA staff here could correct me on this, but I think it would be an 8-hour three exceedance form at 80. That is not there. But probably something in that 10 to 12 percent would be it.

Senator LIEBERMAN. Again recognizing that we may not be able to do anything about background levels of pollution, doesn't it make sense to help the people that we have some ability to help? In other words, if there is that range of hospital admissions resulting from changes in the standards—13 to 44 percent is what I read in your prepared testimony is a significant reduction.

Dr. MCCLELLAN. We can do a lot with statistics and numbers. We probably need to go up to the excess admissions line up there and take a look at the 120 under the 8-hour five exceedance, 80 ppb and say that we are looking at that 120 versus the 385 as is, versus the 210. But at the same time, keep in mind that the background of 28,000 cases out there. One of the things we better be doing is making certain that we are looking at the real issue: What are the factors that truly cause asthma? We need to get away from this single pollutant finger-pointing approach to it and look at the fact that today environmental diseases are multi-factoral and we should neither overstate or understate what the impact of a particular standard will do.

Senator LIEBERMAN. I have one last question, Dr. Thurston.

Since this chart comes from work you have done, I note in your testimony that you have some questions and criticisms about the use of this—including EPA's use—because it fails to consider hospital admissions for other respiratory effects, such as bronchitis or pneumonia. Therefore the risk assessment may be understated by a factor of two.

Can you comment on that?

Dr. THURSTON. This only considers asthma. But in our studies we also looked at total respiratory. When you look at various cities—not just rely on one city—basically what we find is that the total respiratory effect is about double that of asthma alone. So you can basically take all these numbers and double them. That would give you a better picture.

Senator LIEBERMAN. Total respiratory effect of ozone?

Dr. THURSTON. Yes.

You have all seen this before. I am looking at this for the first time and it is a little confusing at first. One of the things it is missing here is how it varies from our present situation. We really don't see what we have from the present standard. We are not now meeting the standard.

It's difficult to make the point without first looking at these numbers. Maybe I could respond to it in writing later. Could I do that?

Senator LIEBERMAN. That would be fine.

Dr. THURSTON. The point is that we really have slowed down in our progress on ozone. Part of the problem is that we are looking at it as a 1-hour peak. Therefore, we have these little pockets where we are regulating it. If we go to an 8-hour standard, we are going to have a more realistic perspective, which is that this is really a national problem that needs to be addressed in a national way. If we do that, we are going to make progress much more rap-

idly than we've been making it because it is a team effort. Therefore, this new standard would get some new credit out of the reductions from "as is" down to the standard, not just compared to the present standard that we are not meeting and this new standard. It is not much of a tightening. The big difference is the way it is going to be implemented.

Senator LIEBERMAN. Everybody seems to agree that the move to the 8-hour standard is appropriate.

Thank you, Mr. Chairman.

Senator INHOFE. Thank you, Senator Lieberman.

Senator CHAFEE.

Senator CHAFEE. Perhaps the panel could explain this very busy chart up there, but let me see if I've got it.

I don't number the first column, and there are after that nine columns. Unfortunately, the numbers aren't under them.

Let's look in the last column—and I will zero in on you, Dr. McClellan. Is this your chart?

Dr. MCCLELLAN. This is a chart which was included in the CASAC Committee's closure letter to the Administrator.

Senator CHAFEE. You made the mistake of making eye contact with me—something we always avoided in law school—so I am calling on you.

[Laughter.]

Senator CHAFEE. The total admissions in New York City on an annual basis due to asthma is 28,470.

Dr. MCCLELLAN. That is correct.

Senator CHAFEE. If you look at the top of that column, that column is under excess admissions—if you look way over to the left—the excess over what? As I understand, it is excess over what there would be if there were no industrial pollution.

Dr. MCCLELLAN. If there were no ozone, a situation that cannot occur. It has background ozone in it.

Senator CHAFEE. So you would reduce those admissions by 385, right?

Dr. MCCLELLAN. Yes, but we would still have 680 attributable to the background ozone, the level which EPA has said is background. That is 40 ppb. Above that we have 385 cases.

Senator CHAFEE. Set aside the background because I think all of us agree that none of us can do anything about the background.

Dr. MCCLELLAN. OK.

Senator CHAFEE. I am trying to get clear in mind just what we are dealing with.

If you then go to—I am always staying on that top line—first what we're saying is that if there were no industrial pollution—forget the background—you would reduce the number of admissions to hospitals from 28,470 by 385 per year. Now we go way back to column one, always staying on the top line. We are dealing with excess admissions.

Because they are not meeting the current—if they met the current standards, they would reduce the number of admissions by 210.

Dr. MCCLELLAN. They go from 385 down to 210.

Senator CHAFEE. We are talking reductions of admissions?

Dr. MCCLELLAN. Your reduction would be the difference between 385 and 210.

Senator CHAFEE. In other words—

Dr. MCCLELLAN. A lawyer once advised me to never do simple arithmetic in a hearing or courtroom. But I will agree that it is probably 175.

[Laughter.]

Senator CHAFEE. But now let's go over to what EPA recommends, which is the next to last column. Are you with me? That is 8H5X. I believe that is what EPA is recommending.

Dr. MCCLELLAN. It is the appropriate number, 80 part per billion, 8-hour averaging time, but here it is five exceedances and the Agency has recommended three. But it is close.

Senator CHAFEE. We can call the next to last column what EPA is recommending?

Dr. MCCLELLAN. Right.

Senator CHAFEE. If EPA's recommendations went into effect, you would find that the excess admissions over perfection would be 120. Am I correct?

Dr. MCCLELLAN. That is correct, when that standard was attained.

Senator CHAFEE. Am I missing something here, or are we really dealing in very, very minor improvements to the health of the citizens of New York City. There are 28,000 admissions currently. If everything were perfect, we would reduce that by 385 per year.

Dr. MCCLELLAN. I think you have grasped the point.

Senator CHAFEE. If EPA's proposed standard went into effect, we would reduce those admissions not by 385 but by 120.

Dr. Thurston.

Dr. THURSTON. The difference would be 385 minus 120, if I am understanding this. So the couple hundred you would reduce, you would have to multiply that by two if you want to consider other people who have respiratory disease. I guess it comes down to whether or not you are one of those people as to whether it is important.

Senator CHAFEE. I think we have to put this in some context. It is all right to say that we don't consider expenses. But indeed we do. Dr. McClellan is active in water matters. When we did the Safe Drinking Water Act we provided for the small communities so that they didn't have to meet the same standards the large communities did.

As you recall, we passed that unanimously out of this committee and the floor of the Senate. It is now the law. All I am trying to do is to get straight in my own mind that for an investment of several billion dollars, and in meeting the EPA standards, we are reducing the number of admissions over what there would be—if there were no problem—by 120. Meanwhile, there were 28,000 admissions for asthma.

Am I on the right track, Dr. Thurston? Where am I going wrong?

Dr. THURSTON. I think we are here to get to the truth, and that is why I am here.

The point is that asthma is a big problem and respiratory disease is a big problem. We as a Nation have said that we are going to protect people from adverse effects of air pollution. In other words,

there are lots of causes of asthma, and most of them we can't do a darned thing about. But this happens to be one that we can.

Senator CHAFEE. We can do very little about it.

Dr. THURSTON. I am saying that this particular pollutant we can do something about. There is a law against these people being adversely affected.

I wish you could have been at that camp with me when the children had their asthma attacks. They don't show up in these statistics. Children who have asthma attacks don't all end up in the hospital, but their effects are very serious.

Senator CHAFEE. I certainly will agree and I want to associate myself with what the chairman said when he opened the meeting here. He said that every single one of us want to attain clean air in this Nation. I have 11 grandchildren and many of them are in Rhode Island.

Dr. THURSTON. I also have family in Rhode Island.

Senator CHAFEE. There is no question that we are concerned. But I do get back to what Dr. McClellan said. Will we get the "biggest bang for the buck?" A very expensive undertaking has been proposed to meet the new standards suggested by the Administrator. From what I see in this chart, you reduce the hospital admissions by a tiny percentage of the total admissions.

Dr. MCCLELLAN. That's what it says, and these are calculations. There are a lot of assumptions built in here. There is a linear model of ozone exposure-response that goes down to background. But I think the chart is very valuable in providing perspective. I think your questions helped illustrate the kind of perspective one needs to draw from this and to recognize that in setting the standard the Administrator has made a policy call. It is not one that is driven to a particular answer by the science.

Senator CHAFEE. Thank you very much, Mr. Chairman. I know we have another panel and I want to hear them.

Senator INHOFE. We are back on schedule, not due to the discipline of the witnesses or the Senators, but that we are dropping our numbers.

[Laughter.]

Senator INHOFE. Dr. Menzel, did you want one last comment?

Dr. MENZEL. Yes, Mr. Chairman.

When I made that comment in response to the question about whether EPA was doing a good job in husbanding its resources, I may have been impolite there. I really did not intend to infer that it was personalized with Administrator Browner. I hope the committee will understand that. It is the culture that I am talking about.

Senator INHOFE. I thank all three of you for taking time out of your schedules to come and testify.

Senator INHOFE. I would now ask our third panel, which is the PM panel—even though we have been transgressing back and forth—to come to the table. I would like to welcome Dr. Anne Smith, vice president, Decision Focus Incorporated; Dr. Joel Schwartz, associate professor of environmental epidemiology, Department of Environmental Health, Harvard School of Public Health, Harvard University; and Dr. Ron Wyzga, target manager, health studies, Electrical Power Research Institute.

We will start with Dr. Smith.

**STATEMENT OF ANNE SMITH, VICE PRESIDENT,
DECISION FOCUS INCORPORATED**

Dr. SMITH. Thank you, Mr. Chairman.

My name is Dr. Anne Smith. I am a vice president of Decision Focus Incorporated. I have 20 years of experience in environmental risk assessment and risk management and a Ph.D. from Stanford University. I have contributed substantially to a number of major air quality policy assessments over the years for EPA, the Grand Canyon Visibility Transport Commission, and for industry organizations. I am honored to have this opportunity to speak with you today. My statement here reflects my personal opinions and not those of my company or any other group.

I compare the situation for PM to the classic shell game. I think that in trying to control the true culprit with PM, we stand the risk of turning over many shells while we try to get at the culprit, and yet get no particular benefit from public health. I will explain why.

There are a number of statistical or epidemiology studies we have been hearing about. These indicate that as ambient PM go up and down, so do health effects. However, when you observe two types of data going up and down together, this doesn't necessarily mean that we have a causal relationship, even if it is statistically significant. For example, if we were to discover an association between heat stress mortality and ice cream cone sales, we wouldn't conclude that we have a causal relationship here, even if it was statistically significant. The error in that conclusion would be obvious to us because we have a very good understanding of the biological processes for heat stress.

This type of biological understanding does not exist at this moment for PM. EPA's peer reviewed criteria document tells us that there is no knowledge of the mechanism, no credible supporting toxicological evidence, and no compelling argument for biological plausibility. It is easy to make big mistakes when you are relying on statistical significance alone. Hence, the criteria document concludes that "much caution is warranted" in using these statistical findings for estimating risks.

How much caution? Recently I did some numerical experiments to explore the likelihood that several specific types of data problems mentioned by EPA could cause significance. To be brief, I found plenty of cause for caution on my own.

The truth is often the opposite of the statistically significant result when there are data problems that are found in all of these studies. PM may not be causing the mortality at all that is being shown in these studies. Other air pollutants, such as carbon monoxide or ozone, could be the real culprit as well as PM. Presently, there seems to be insufficient recognition of the magnitude of this particular uncertainty for PM.

So, what if you could be convinced that there is a fine particle effect? Then would a PM_{2.5} standard be sufficient for health protection? No. The shell game analogy still applies here.

Look at what PM_{2.5} consists of. Unlike any other criteria pollutant, PM is made up of many different types of components and they are from many different types of sources. Even if we believe

the problem stems from PM, we still don't know which components might be potent, so we don't know which sources to control to get at the culprit. Statistical studies do not help us narrow down the list of likely culprits. They just don't have the relevant data to do that.

Biological hypotheses exist and they do not help us much either in deciding what to control because each one suggests a different set of control actions would be necessary to protect public health. For example, some think the problem might be from a type of particle called the ultra fine. These are about 100 times smaller than the typical particle accounted for in PM_{2.5}. Science tells us that if we want to reduce human exposures to ultra fine particles, then we need to apply controls to local sources, such as gasoline-fired automobiles.

But another hypothesis is that there is an effect caused by the accumulation of particles in the lungs. If we believe this hypothesis, then protection would require controls on only non-soluble types of particles such as soot and road dust, a totally different set of sources.

There are many more hypotheses about potential culprits. It seems unlikely that all of them would be valid. So we don't really know what to control. I want to make it clear that this is not like the situation with tobacco smoke, where there is a single control action—quitting—that is sufficient to control all the constituents. Thus we can get certainty that we will control the still unknown culprits in tobacco smoke.

How has EPA communicated these uncertainties to the public? Despite clear warnings against it in the criteria document, EPA's risk and its benefits estimates use the statistical results as if they can be accepted at full face value. In the case of the benefits range you have heard from \$58 billion to \$120 billion a year, recognition of uncertainty has devolved down to using two point estimates from only two individual studies. The benefits range does not reflect the uncertainty in whether PM is the causal factor. The benefits range does not reflect the uncertainty about which type of fine particle might be the culprit and whether those types might be controlled under a fine particle standard.

These and other very significant certainties have simply been presumed away. Thus the billions of dollars of benefits estimates are much more uncertain than EPA has indicated, and in fact could be very small—perhaps even zero.

I am not suggesting years of delay. I think we could have more complete communication to the public of uncertainties, and more complete consideration of how alternative approaches to regulating could deal with these uncertainties.

Thank you.

Senator INHOFE. Thank you, Dr. Smith.

Dr. Schwartz.

STATEMENT OF JOEL SCHWARTZ, ASSOCIATE PROFESSOR OF ENVIRONMENTAL EPIDEMIOLOGY, HARVARD UNIVERSITY

Dr. SCHWARTZ. Thank you, Mr. Chairman. And thank you for inviting me.

I would like to summarize my remarks.

Senator INHOFE. Without objection, your prepared statement will appear in the record.

Dr. SCHWARTZ. I would like to make several points. First, EPA is in fact not out on the science in the proposed standards, but actually lags behind the conclusions of many governments in western Europe and international scientific bodies. The cautions and arguments you have heard put forth have all been considered and made before and been considered by these bodies in leading to the conclusions that they did. Second, there is evidence that fine combustion particles from all the major choices are in fact associated with these health endpoints. I will explain that. Third, there actually are recent toxicological findings which confirm the epidemiology findings in considerable detail. Fourth, moving to a PM_{2.5} standard is appropriate and hasn't been made before.

You have heard about the size of these particles. Particles less than 2.5 microns are predominantly from combustion—from burning things, cars, industrial processes—what we classically think of as pollution. The bigger particles are wind-blown dust. So the question is, Should we focus our controls on dust, or these combustion particles?

In terms of the scientific consensus, more than a year ago the British government's version of CASAC reviewed the evidence on particles, concluded that there was a causal association with mortality, and recommended that the British government set a new particle standard, which is one-third of the current U.S. particle standard. They wanted a PM₁₀ level of 50 on a 24-hour basis to correspond with 30 at PM_{2.5}.

Second, as you have already heard from Dr. Lippmann, the World Health Organization has developed a criteria document on particles. They have concluded that this is a causal association after examining all the evidence and have drawn up, in fact, dose response relationships that they have recommended that people use to estimate how many lives will be saved at various different standards. Those folks suggest that indeed there are tens of thousands of early deaths that would be avoided per year by the proposed EPA standards.

The Swiss government has just conducted their review and has again recommended a standard that is one-third the current U.S. standard. These are substantial tightenings.

Dr. Wolff talked about the 24-hour standard. I think the annual average for PM_{2.5} is actually much more important. It seems to me that that was a critical part of the staff paper that was approved by CASAC when they voted to approve the PM_{2.5} standard. It was with accepting, by their majority vote, the range of 12 to 20. EPA has picked a number of 15, which is in the range that has been approved.

In terms of which particles matter, we have a lot of information on this because studies have been done in a lot of different places. In the northeast, the dominant source of fine particles are in fact sulfates. We see lots of studies showing association with fine particles or with particles or with sulfates directly. So it appears that sulfates are associated with these adverse health effects. They are one of the particles that matter.

On the other hand, in Santa Clara, CA, there essentially are no sulfates in the air in the winter. It seems to be wood smoke, and they still found results. Other studies have been done in places where the dominant source is gasoline or diesel engines.

In terms of toxicology, Dr. Godleski at Harvard has done a study exposing animals to concentrated particles from the Boston air for 3 days in an average concentration under 100 micrograms. That is permissible under current EPA standards. Little happened to the healthy animals, but 37 percent of the bronchitic animals died after 3 days of exposure to permissible concentrations of fine particles. So we know that fine particles can kill animals at relevant concentrations that are seen today when they have illness.

On the other hand, 10,000 micrograms per cubic meter of dust of coarse particles from Mount Saint Helens had no effect in epidemiology studies that were done following that eruption. So we know that focusing on the fine particles is where we need to put our attention.

Finally, there are other toxicology studies that have taken Washington, DC particles, separated into fine and coarse, instilled them into the lungs of animals, and there was substantial toxicity from the fine particles, but not from the coarse particles. This confirms that particles can have a toxic effect, which supports the epidemiology, and also suggests that it is the small ones that matter. There are also studies using data from Mexico City and elsewhere.

Last, I would like to provide one other piece of evidence. This has to do with the issue Dr. Wyzga will raise about measurement error in coarse particles. There is also measurement error in fine particles, though it is less appreciated, because the volatile ones disappear from the filters. But if you average your measurements over long periods of time, these day-to-day fluctuations tend to average out. I have provided you with two pictures at the back of my testimony from a study published last year—using data from that study. One shows the percent of children in the 24 city studies with abnormal lung function, controlling for individual risk factors, plotted against the fine particle concentrations in those towns.

Fortunately, the fine particle concentrations and coarse particle concentrations didn't correlate that high, so you can do the same plot for coarse particles. For the fine particles, the percent of children with abnormal lung function triples as you go from low to high. For the coarse particles, there is no association at all.

Thank you.

Senator INHOFE. Thank you, Dr. Schwartz.

Dr. Wyzga.

STATEMENT OF RON WYZGA, BUSINESS AREA MANAGER, AIR QUALITY, HEALTH AND RISK STUDIES, ELECTRIC POWER RESEARCH INSTITUTE

Dr. WYZGA. Thank you.

I am Dr. Ronald Wyzga. I work at the Electrical Power Research Institute in Palo Alto, CA. By training, I have my doctorate in biostatistics from the Harvard School of Public Health.

I have undertaken research in this area for many years. I am going to give you my personal views, which do not reflect those of my institute nor of any of my associates.

I agree with Joel and others that there are many positive studies that show a statistically significant association between health endpoints and exposure to particulate levels. I have undertaken many of these studies myself, and my institute has funded many of these studies. The key question is, Do we have enough evidence? Or do we really believe that if we were to reduce particulate levels in today's environment, would there be public health benefits?

I think the correct answer to that is that no one really knows. Let me tell you why. We have all these positive studies, but we have to temper them with several factors.

First of all, there are negative studies. We need to include these and mention these as well.

Second, recently there have been—

Senator CHAFEE. There are negative studies showing that the other studies aren't accurate?

Dr. WYZGA. There are studies that find no association between health endpoints and exposure to particulates.

There is another set of studies that have taken studies that were originally positive that have reanalyzed them and have come to the conclusion that we cannot say that particulates are responsible for those health endpoints. These studies have been funded by a wide variety of institutions from EPA to private industry. So we are looking at a whole range of individuals who have reanalyzed these data sets.

Third, there is really no one correct way to analyze a data set. These are very complex data sets and there are lots of different statistical methods that are appropriate that can be used to analyze these. Since we can't say what's right, it basically gives people a lot of flexibility in the tools they use in analyzing a data set. Let me say that even in some recent work we have done we use some of these tools and we get some remarkably silly results.

Fourth, we really can't say if it is particulates or some other agent in air pollution that is associated with health outcomes in these studies. Lots of pollutants occur at the same time. It is very difficult to pinpoint which one is causing any specific health effects, if it is one pollutant in particular.

We have a curious disconnect between the personal exposures of people to particulates and what is measured with the ambient monitor. We need a better understanding of how what we are personally exposed to relates to what is measured out there.

EPA, in its proposal, says that there is no accepted biological explanation of the results of the statistical model.

I firmly believe that when you look at the data, regardless of how you look at the existing data, and you compare what we know about the health effects of PM_{10} and the health effects of $PM_{2.5}$, you see absolutely no advantage for $PM_{2.5}$.

In summary, I see our situation as very much akin to the solving of a jigsaw puzzle. We are looking for the picture that the puzzle is going to tell us. We have some of the pieces, such as positive studies, that are suggesting that there is something going on here. But we have some missing pieces; for example, the biology. We have other pieces that don't seem to fit, the negative studies, the studies that contradict each other, the apparent disconnect between personal exposure and what is measured at the monitoring station,

the fact that it is difficult to disentangle the different pollutants. All of these pieces are there as we scramble to understand what we can see.

I don't know if when we look at the finished product—are we going to see that there are particulate effects on health? Are we going to see that these associations are part of an illusion? Or are we going to learn that something completely unexpected is occurring, something that we have no knowledge or foresight today of what the answer is going to be?

Senator INHOFE. Thank you, Dr. Wyzga.

Let me start with Dr. Smith.

I know I have learned a lot in the last 3 hours. Can you explain to me the biological mechanism for PM_{2.5}?

Dr. SMITH. What I have stated comes straight from the criteria document. There is no plausible biological mechanism that has been—

Senator INHOFE. Would you say that more studies are needed to determine what the mechanism is?

Dr. SMITH. Yes, that's right.

Senator INHOFE. About how many different substances are there at the size of PM_{2.5}?

Dr. SMITH. There are maybe about six different categories of different types of chemicals. They all come from quite different sources. One of the key categories would be sulfates, which come from mainly coal burning. Another key category would be nitrates that come from NOX emissions, which come from many combustion sources, automobiles, and power plants—

Senator INHOFE. There are many?

Dr. SMITH. There are many.

Senator INHOFE. Would it be conceivable that a community could protect itself or control a substance such as nitrates only to find that 5 years from now or 10 years from now it has no effect on the results that we have been looking at today?

Dr. SMITH. Right. That is the essence of what I was trying to say.

Senator INHOFE. Dr. Schwartz, I understand that your studies were primarily what the EPA was relying on when they came up with their recommendations. Therefore, your testimony is very important. I understand that some of your critics—some of the scientists who disagree with you—have not been able to get access to some of your data.

I have to say this critically of you, Dr. Schwartz, because we have a rule in this committee that we explain to all potential witnesses that we want the testimony to be submitted 48 hours before the appearance, which would have been at 9 o'clock on Monday. We didn't receive your's until this morning. The reason that is significant is that we do take the testimony and we read it, our staff reads it, and it gives us an opportunity to study it prior to the meeting. It puts us at somewhat of a disadvantage.

Dr. SCHWARTZ. I understand that. First of all, I faxed it to the committee yesterday afternoon. I don't know why you didn't get it. I gave it to my secretary with the fax numbers. In terms of why it was yesterday rather than earlier, I was asked rather late in the game to come down here and testify, and I didn't have a lot of time to prepare my testimony.

Senator INHOFE. Dr. Schwartz, you were asked at the same time as everyone else. In fact, I believe Dr. Menzel was asked after you.

I only say that because there is a reason for this. I think on future committees we are really going to adhere to that.

On your six-city study—I think this is probably the principal research upon which the EPA has made its recommendation—at least I have been told that and I saw a document here that leads me to believe that—there are so many variables. As a general statement, don't you think that a scientist's prejudgment can come in by how they weight the variables that are out there?

Dr. SCHWARTZ. I certainly think it is true, as Ron said, that different people analyze data differently. That is one of the reasons there is a CASAC review process. In the course of spending a year in CASAC and a year before that in criteria document workshops going over all the issues and how they are analyzed, people start to come to some consensus about what is appropriate. First of all, my paper went through CASAC review and they could have told EPA to ignore it because it wasn't appropriate. But also some of the methods I used to control for weather and other things were things that were getting favorable reviews in the CASAC review process.

But I would not say that my paper was the basis of the decision to go to PM_{2.5}. There are other studies, like Dr. Thurston's epidemiology study in Toronto, which also shows that coarse mass is not predictive of hospital admissions, but the fine particles are, as well as the toxicology studies where we see that the coarse particles are not toxic to animals' lungs, and the fine ones are.

Senator INHOFE. It is my understanding that the National Institute of Statistical Sciences reexamined your Birmingham study and controlled for humidity and got different results. I have a few other examples, too.

I understand that can happen with anyone's study. I understand it more now than I did 3 hours ago.

Dr. Wyzga, you were the last one to testify. I want to go back to the first one to testify, Dr. Wolff.

Senator INHOFE. Senator Chafee.

Senator CHAFEE. Sorry to butt in, Mr. Chairman. I really have to go, but I wanted to ask one question to Dr. Schwartz.

You refer to the Godleski study at Harvard. When was that? The only reason I am asking is that I believe it is rather recent.

Dr. SCHWARTZ. That was presented last May at the annual meeting of the American Scholastic Society, as was the study on the fine versus coarse particles from Washington.

Senator CHAFEE. Dr. Smith, when you looked at the criteria documents, I understand quite clearly that it is a stack of documents. Do you know whether the Godleski study was in there?

Dr. SMITH. It was available in abstract form at the time the criteria document was published. As far as I know, I have not been able to get a hold of anything in any more detail. And there are a number of considerations and concerns associated with that. But the results were known at the time the criteria document was published.

Senator CHAFEE. Mr. Chairman, I want to join you in saying—

Dr. SCHWARTZ. Dr. Godleski made a detailed presentation to CASAC of the results of that study and went into it in great detail and was asked questions.

Senator CHAFEE. Mr. Chairman, I want to join with you in thanking this panel and the others for coming here. We greatly appreciate it. As Senator Hutchinson said, this is a very complicated subject. We are all learning and you have greatly increased our knowledge.

Thank you very much.

Senator INHOFE. Thank you, Mr. Chairman.

Dr. Wyzga, I know you were here when I was speaking to the first witness, Dr. Wolff. I am trying to sort this out and get it to something that we understand as people who are not scientists.

You talked about a couple of factors. You had your risk factors. I think it was Robert Temple who said that my basic rule is that if the relative risk isn't at least three or four, forget it. This I understand is somewhere around 1.0 to 1.2 percent and that there is no identifiable biological mechanism for PM.

We are looking at two very significant bottom line things here. Would you comment as to Dr. Wolff's answer and as to whether or not you agree with that?

Dr. WYZGA. Basically what we are talking about here is relative risk in the order of 1.05 to 1.07, which is really minuscule. What worries me is that given the tools that we have and the data we have, are we perhaps even biasing ourselves and getting some relatively silly answers?

One of the things I have done recently is to take some very unlike data sets and I am getting very surprising results. If I use the same models that relate particulate air pollution to health, I can explain the number of deaths each day in San Jose, CA, by Philadelphia air pollution mortality data. I can take the number of deaths each day in the United States and explain those using the same techniques with Philadelphia particulate data. I can take the number of births each day in the United States and I can explain those with Philadelphia total suspended particulate data.

These results are silly and make absolutely no sense. I don't understand them. One of the things I need to do is to try to find out why I am getting these silly results. Does it mean that we are really doing something inherently wrong? Does it mean that somehow Philadelphia particulate data are the key to the world? Or does it mean that I just happened to fall upon a very strange artifact?

I don't know, but it is something that really disturbs me, particularly when I see these very small relative risks.

Senator INHOFE. Thank you, Dr. Wyzga.

Dr. SCHWARTZ. May I respond to that?

Senator INHOFE. Sure.

Dr. SCHWARTZ. On the issue of small relative risks, I think we have to realize that it is 1.07 and that certainly could be a matter of concern to people. That is why it is important to try to look at multiple studies as well as at animal studies. But it is also important to know that when you look at very common health outcomes, that is where you tend to see relative risks. You don't see relative risks to dying of heart disease, because 40 percent of the popu-

lation dies of it. It is pretty hard to have one risk factor that makes you four times more likely than that.

In fact, the relative risk of having a heart attack for a blood pressure of 95 compared to a blood pressure of 85 is 1.1. Yet we have one-third of the adult population taking anti-hypertensive medication because we think it can lower their blood pressure by 5 to 10 millimeters and produce that change. So it is certainly the case that when we look at common outcomes there are plenty of things that have relative risks in those ranges.

Senator INHOFE. I have one last yes or no question to all three of you.

You heard me read the magazine article from Science—and I assume that is a credible publication—“Since there is no identifiable biological mechanism and the risk factors are so low, are these studies less than stunning results?”

Dr. Smith.

Dr. SMITH. I think I would like to go to EPA’s own quote from the criteria document, which refers to the same circumstances. “Much caution is warranted in using these results.

Senator INHOFE. Dr. Wyzga.

Dr. WYZGA. I think these studies raise a concern, but it is totally unclear to my mind if the concern is about particulate matter or some other pollutant, or some other factor.

Senator INHOFE. I knew we wouldn’t get a one-word answer.

[Laughter.]

Senator INHOFE. And I know we won’t get it from Dr. Schwartz.

Dr. SCHWARTZ. Given the wealth of studies and the ranges that have been reported for different outcomes that the conclusions of the World Health Organization panel that these are likely causal associations is a warranted one.

Senator SESSIONS.

Dr. Schwartz, with regard to the Birmingham study, you did not include the humidity in your report, did you not?

Dr. SCHWARTZ. In that study, no. I haven’t seen humidity being put in lots of other studies. Frankly, I am sure these people get a different answer than I do. I am not sure that the only difference between our analyses is controlling for humidity. I suspect it is due to other things because other people I talked to also don’t tend to see important effects of humidity.

Senator SESSIONS. The point is that they used your studies. When they just applied and factored in the humidity that was present during the days in question, they got no difference and no adverse effects from their conclusion of your very own study.

Do you dispute that?

Dr. SCHWARTZ. I haven’t examined in detail what they have done. If they tell me that they did something and those are the results, I believe them. Then people could look in detail at what they did and what I did and decide what they think.

Senator SESSIONS. We are all uncertain about a lot of things. I guess it would be fair to say that you can’t be certain whether humidity did or did not have an effect. Is that correct?

Dr. SCHWARTZ. That’s correct.

Senator SESSIONS. Dr. Smith, you mentioned a cost factor of billions of dollars that might be involved in the air. I know we aren’t

supposed to talk about that, but it seems to me that we could think in terms of billions of dollars being spent on asthma research might save more asthmatics than billions of dollars on this.

Do you have any thoughts on that? Have there been any studies on that kind of thing?

Dr. SMITH. I haven't really followed the studies on research for asthma, per se, but there is always a question in any policy debate as to whether the dollars could be spent more effectively in another manner. I have not tried to address that. My comments are more aimed at the need to consider alternative ways of setting a standard so that we can get a higher chance of getting at whatever the culprit is.

Dr. WYZGA. Could I add one thing to the asthma question?

Senator SESSIONS. Yes.

Dr. WYZGA. One of the things that concerns me is that there is general acknowledgement among the community of pulmonologists—in fact it is acknowledged in the EPA's proposal—that if there is an effect of asthma on asthmatics, it is the coarse particles deposited in the upper airways. What is curious—and EPA then calculates how many asthmatic attacks can be saved and admissions to hospitals—the larger fraction would be regulated under PM₁₀. What is proposed is a relaxation of PM₁₀. There could be five times as many days in which the current PM standard would be violated under the new proposal than under the existing ones. So if these asthma effects are real, and if we want to protect asthmatics, what is being proposed is not the answer.

Senator SESSIONS. Dr. Schwartz, you mentioned the ultra fine particles. Do you have any feeling that there is any distinction between the size of the particles and the adverse health effects, whether it might be 1.5 particles that really cause the damage rather than the 3.0 particles? Do you have any knowledge?

Dr. SCHWARTZ. That is a good question, Senator.

I am relatively convinced that the particles larger than 2.5 microns—which are dust particles basically—are not important for most of the health effects. It is possibly important for asthma, but even there I am not sure. But for everything else, I am relatively convinced that that is not what matters. It is really the combustion particles that matter.

Combustion particles are less than 2.5 microns, but mostly they are less than 1 micron in size. Ultra fine particles come right off the combustion process. You get these very, very small particles and then they agglomerate up and tend to get bigger. They tend to grow up to things that are around .3 microns in size, roughly.

The other major source of particles comes from combustion, but it doesn't start out as a particle. Sulfur dioxide will come out of a smokestack, power plant, or whatever, travel downwind and react in the air to form sulfates, which are particles that react with ammonia and you get ammonium sulfate. That is a particle. Those tend to be a little bigger. They tend to be around .7 microns. But most of them are less than 1 micron in size.

I think that yes indeed probably the stuff we are talking about is less than 2.5, but it is probably mostly less than 1 micron.

The hypothesis has been raised that maybe it is really the ultra fines when they are very, very small. That is a hypothesis which

I am in fact investigating with a group of people I am collaborating with in Finland.

It has the disadvantage that those particles basically don't get indoors whereas the sulfate particles do. By the time those things get indoors, they have agglomerated up and are bigger. So it is hard to see how people are being exposed to it.

Senator SESSIONS. It is a complicated subject.

Dr. SCHWARTZ. It is a complicated subject. I am certainly looking at it. I am confident it is less than 1 micron. Whether it is between .3 and .8, I don't know yet.

Senator SESSIONS. Dr. Wyzga.

Dr. WYZGA. I would agree with Joel with respect to ultra fines. I am personally a little skeptical about the hypothesis, but it is one that is out there.

One of the things I have done recently is take every single study that has looked at both PM_{10} and $PM_{2.5}$. If you look at the average pollution level we have today, and assume a 10 percent change in the pollution level of either PM_{10} or $PM_{2.5}$, and estimate the benefits of reducing them 10 percent, in no study—and we have looked at every one that is out there—do you find an advantage for $PM_{2.5}$. In some studies you find advantages for PM_{10} . It is something that I really urge the Agency and other scientists to do, to make such a table. We have generated it.

I am now working on a paper that we will be submitting for publication based on this work, but I would be happy to submit even the preliminary results to this group or any other group to show them what we have done.

Senator SESSIONS. Then you would conclude that it would be unwise for our Nation to undertake a huge national commitment to a policy that at this point you feel the data is uncertain as to whether we would receive a benefit from it?

Dr. WYZGA. Yes, sir.

Senator SESSIONS. Thank you.

Senator INHOFE. We thank you very much for coming, all three panels. We know how valuable your time is. You have been very, very helpful. We appreciate it so much.

The record will be kept open for members for questions for another 48 hours.

We are recessed.

[Whereupon, at 1 o'clock p.m., the subcommittee was adjourned, to reconvene at the call of the chair.]

[Additional material submitted for the record follow:]

PREPARED STATEMENT OF DR. GEORGE T. WOLFF, CHAIRMAN, CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE (CASAC), AND ATMOSPHERIC SCIENTIST FOR THE GENERAL MOTORS COMPANY

LEGISLATIVE BACKGROUND

In 1963, the Clean Air Act (CAA) was passed by Congress directing the then Department of Health Education and Welfare to prepare "Criteria Documents" which would contain summaries of the scientific knowledge on air pollutants arising from widespread sources. The 1970 CAA required the EPA Administrator to set National Ambient Air Quality Standards (NAAQS) for the identified "criteria" pollutants and gave the Administrator the authority to revise the NAAQS in the future and to set additional NAAQS as needed. At that time, 6 air pollutants were designated as criteria pollutants: photochemical oxidants (later became ozone), sulfur dioxide, non-methane hydrocarbons (later dropped as a criteria pollutant category), nitrogen di-

oxide, carbon monoxide, and total suspended particulate (later changed to PM₁₀, which includes only particles with an aerodynamic diameter less than or equal to 10 microns). In 1971, EPA established NAAQS for all six.

The absence of a mechanism for a periodic reassessment of the initial NAAQS, prompted Congress to add into the 1977 CAA amendments a requirement that the NAAQS be reevaluated every 5 years. In addition, the 1977 amendments created a new committee—the Clean Air Scientific Advisory Committee (CASAC), to review the periodic reevaluations. Organizationally, CASAC is housed within EPA's Science Advisory Board (SAB)¹ and functions as one of the ten standing committees of the SAB. However, unlike most of the other standing committees of the SAB, CASAC reports directly to the EPA Administrator rather than through the Executive Committee of the SAB.

Congress specified a number of responsibilities for CASAC. One was to provide independent advice on the scientific and technical aspects of issues related to the criteria for air quality standards. The CASAC charter² states some of their functions:

Not later than January 1, 1980, and at five year intervals thereafter, complete a review of the criteria published under section 108 of the Clean Air Act and the national primary and secondary ambient air quality standards and recommend to the Administrator any new national ambient air quality standards or revision of existing criteria and standards as may be appropriate.

Advise the Administrator of areas where additional knowledge is required concerning the adequacy and basis of existing, new, or revised national ambient air quality standards.

Describe the research efforts necessary to provide the required information. Advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and

Advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

Previous activities of CASAC prior to 1985 have been summarized by Lippmann.³ Concerning the membership of CASAC, the charter states:

The Administrator will appoint a chairperson and six members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies for terms up to 4 years. Members shall be persons who have demonstrated high levels of competence, knowledge, and expertise in the scientific/technical fields relevant to air pollution and air quality issues.

For any NAAQS review, a CASAC Panel is constituted to conduct the review. A Panel consists of the seven regular members plus a sufficient number of consultant members so that the broad spectrum of expertise needed to fully assess a particular issue is covered on the Panel. These consultants are generally selected from EPA's Science Advisory Board (SAB)¹ or from a pool of about three-hundred consultants maintained by the SAB. However, certain issues have required going outside of the SAB and the SAB consultant pool to obtain a particular expertise. For the ozone NAAQS review, the panel consisted of 15 individuals including physicians, epidemiologists, toxicologists, atmospheric scientists, plant biologists, risk assessment experts and an economist. For the PM review, the panel consisted of 21 scientists.

THE NATIONAL AMBIENT AIR QUALITY STANDARDS AND THE OZONE REVIEW PROCESS

There are two types of NAAQS: primary and secondary. Primary NAAQS are set to protect human public health. Secondary NAAQS are set to protect against adverse welfare effects which include protection of plants, animals, ecosystems, visibility, etc.

The major steps in the NAAQS review process are illustrated for ozone in Table 1. EPA began drafting the Criteria Document (CD), which summarizes all of the relevant science on the sources, chemistry, effects, etc. of ozone, in the middle of 1993. Recent Criteria Documents have become mammoth undertakings. The first ozone Criteria Document,⁴ published in 1970, summarized the relevant science in 200 pages. The present Criteria Document⁵ is a three volume set and contains over 1500 pages. A draft Criteria Document was sent to the CASAC Panel in June of 1994.

The Staff Paper (SP) contains the Agency's recommendations for the range and form of the NAAQS along with the justifications for the recommendations that are drawn from material contained in the Criteria Document. In the past, the CASAC review of a Criteria Document was completed before the Staff Paper was written

so that the Staff Paper would reflect the science contained in the final Criteria Document. The reviews of both the Criteria Document and Staff Paper are iterative processes that usually involve two to three revisions to both of the documents before CASAC reaches closure, and, in the past, the entire process took several years to complete. However, this review was on an accelerated schedule because of a previous lawsuit filed by the American Lung Association (ALA). In the previous review, CASAC came to closure on the Staff Paper in 1989. When EPA failed to complete the last two steps listed in Table I by October of 1991, the ALA and other plaintiffs filed a suit to compel EPA to complete its review. The U.S. District Court for the Eastern District of New York subsequently issued an order requiring the EPA Administrator to announce its proposed decision by August 1, 1992 and its final decision by March 1, 1993. EPA's decision was to retain the existing 1-hour standard of 0.12 ppm, but noted that since there were many potentially important new studies published since the last Criteria Document was written, they would complete the next review of the ozone NAAQS as rapidly as possible. The ALA sought judicial review of this decision, but because of EPA's intention to complete the review as rapidly as possible, the ALA granted EPA a voluntary remand of the petition for review. To accomplish the accelerated review, some of the steps listed in Table I were conducted to some extent as parallel tasks rather than sequential tasks. In particular, a draft of the Staff Paper⁶ was sent out for CASAC review in February of 1995 even though closure on the Criteria Document did not occur until November of 1995.

As shown in Table 1, CASAC reached closure⁷ on the third revision of the Criteria Document in 15 months. CASAC also reached closure⁸ in November 1995 on the Staff Paper after a nine month review process and two Staff Paper revisions. The proposed NAAQS were announced in the December 13, 1996 Federal Register. The last step in the process, EPA's promulgation, is scheduled to be published in the Federal Register on or before June 28, 1997. A public comment period for the December 1996 notice will close February 18, 1997.

HISTORY OF THE OZONE STANDARD

The history of the ozone NAAQS is summarized in Table 2. Additional details are contained in the Staff Paper.⁶ In the Staff Paper, EPA recommended that the existing 1-hour NAAQS of 0.12 ppm be replaced with an 8-hour average NAAQS within the range of 0.07 ppm to 0.09 ppm with one to five allowable exceedances per year averaged over a three year period. The range of stringency from the most stringent (0.07 ppm with 1 allowable exceedance) to the least stringent (0.09 ppm with 5 allowable exceedances) is substantial. In the December 1996, notice, EPA proposed an 8-hour NAAQS of 0.08 ppm. To be in attainment, the average of the third highest in each year for 3 years could not exceed 0.08 ppm. At this level, the new NAAQS is significantly more stringent than the present 1-hour NAAQS when the resulting number of nonattainment areas are considered. With the present NAAQS, 68 Metropolitan Statistical Areas (MSAs) where ozone was monitored through September, 1996 did not meet the standard. This number would jump to 140 with the new 8-hr NAAQS of 0.08 ppm. However, this does not tell the entire story because many of the counties in between MSAs do not now have ozone monitors because they meet the present NAAQS. Some of these counties would become nonattainment with a more stringent NAAQS.

As pointed out in the Criteria Document⁵ and the Staff Paper,⁶ the 1-hour daily maximum background ozone averages between 0.03 to 0.05 ppm. This is the average 1-hour maximum ozone that could be expected during the summer in the continental U.S. in the absence of sources of anthropogenic precursor emissions in the U.S. In rural areas, which experience broader ozone peaks than urban areas because of the lack of ozone scavenger emissions, the maximum daily 8-hour background ozone concentration would be expected to be only slightly less than the 1-hour maximum background of 0.03–0.05 ppm. Consequently, with an 8-hour NAAQS being considered, background ozone becomes a more important consideration.

OZONE HEALTH EFFECT STUDIES: RESULTS AND IMPLICATIONS

The ozone review relied mainly on four broad types of health effect studies: animal studies, controlled human chamber studies, field studies of ambient exposures, and hospital admission studies. The main use of the animal studies was to gain insight on the mechanisms by which ozone produces biological responses and damage to the respiratory system. In the controlled human exposure studies, individuals were typically exposed to ozone concentrations slightly above, at, or below the present NAAQS for a number of hours (~6 hours is the most common) while engaged in light to heavy exercise. Before, during and after the exposure the individual lung

functions (such as FEV1 which is the maximum volume of air that can be expired in one second) are monitored and any symptoms (cough, shortness of breath, chest pain, etc.) are noted. These studies have produced two important results. First, for one or two hour exposures, decrements in lung function tests and symptoms were noted in individuals not engaged in exercise *only* at concentrations greater than three times the present NAAQS. However, some exercising individuals experience decreased lung-function test performance and symptoms even at concentrations at or below the present NAAQS when exposed for multiple hours. This is one of the pieces of evidence that suggested a multiple hour (8-hours) NAAQS is a better measure of response than a 1-hour standard.

The field studies consisted of summer camp and adult exercise studies. In the summer camp studies, children, engaged in the normal physical activities that occur at summer camps, participated in lung function testing and the results were compared to the ambient ozone concentrations. In the adult exercise studies, lung function tests were administered to joggers before and after they ran outdoors and the test results were also compared to the ambient ozone concentrations. The results of both types of studies showed a small but statistically significant relationship between decreased performance on the lung function tests with increasing ozone at concentrations at and below the present NAAQS. These results are consistent with the controlled chamber studies and reinforce the evidence that an 8-hour NAAQS is a better measure of response than a 1-hour NAAQS. *Furthermore, since the relationship between the lung function test results and ozone appears to be linear, there may not be a threshold concentration below which biological responses will not occur.*

The hospital admission studies examined the relationships between daily ozone consistently shown an apparent linear relationship in various North American locations between ozone and the admissions, and EPA has assumed that this relationship is cause and effect. The relationship has been shown to remain even when considering only concentrations below the present NAAQS. Thus, there is no evidence of a threshold concentration and this reinforces the conclusion from the field studies.

CASAC'S INTERPRETATION AND RECOMMENDATIONS ON OZONE

It was the consensus of the CASAC Panel that there only be one primary NAAQS, either an 8-hour or a 1-hour NAAQS. Even though an 8-hour time-frame appeared to be a better measure of response, the Panel acknowledged that the same degree of public health protection could be achieved with either an 8-hour or a 1-hour NAAQS at the appropriate level. It was also the consensus of the Panel that the form of the new standard be more robust than the present one. The present standard is based on an extreme value statistic which is significantly dependent on stochastic processes such as extreme meteorological conditions. The result is that areas which are near attainment will randomly flip in and out of compliance. A more robust, concentration-based form will minimize the "flip-flops," and provide some insulation from the impacts of extreme meteorological events.

The Panel felt that the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations. Based on information now available, it appears that ozone may elicit a continuum of biological responses down to background concentrations. It is critical to understand that a biological response does not necessarily imply an adverse health effect. Nevertheless, this means that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an "adequate margin of safety" is not possible. It further means that risk assessments must play a central role in identifying an appropriate level.

To conduct the risk assessments, EPA had to identify the populations at risk and the physiological responses of concern, develop a model to estimate the exposure of this population to ozone, and develop a model to estimate the probability of an adverse physiological response to the exposure. EPA selected a small segment of the population, "outdoor children" and "outdoor workers," particularly those with pre-existing respiratory disease as the appropriate populations with the highest risks. The Panel concurred with the Agency that the models selected to estimate exposure and risk were appropriate models. However, because of the myriad of assumptions that are made to estimate population exposure and risk, large uncertainties exist in the model estimates.

The results of two of the risk analyses are presented in the Staff Paper⁶ and are reproduced in Tables 3 and 4. It should be noted that the numbers in these Tables differ slightly from the numbers presented in the closure letter⁸ which were based on EPA's estimates that were in the August 1995 draft of the Staff Paper. The numbers in Tables 3 and 4 are based on EPA's latest estimates contained in the final June 1996 Staff Paper. The biggest change is in the total number of asthma hospital

admissions in Table 5 which is 50% lower than those in the closure letter. The difference is that the closure letter used annual admissions, but the numbers in Table 4 are six-month (ozone season) numbers. By using a six-month basis for the total admissions, the percentage of annual admissions due to ozone exposure is inflated by a factor of two.

The ranges from ten model runs of the risk estimates across nine cities for outdoor children are presented in Table 3. Because of the large number of stochastic variables used in the exposure model, the exposure estimates vary from run to run. However, the ranges presented in Tables 3 and 4 are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates.

Based on the results presented in these and other similar tables presented in the Staff Paper and an acknowledgment that all the uncertainties cannot be quantified, the CASAC Panel concluded that there is no "bright line" which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health (this includes the present standard). For example, the differences in the percent of outdoor children (Table 3) responding between the present standard (1H1EX at 0.12 ppm) and the most stringent proposal (8H1EX at 0.07 ppm) are small and their ranges overlap for all health endpoints. In Table 4, the estimates in row 1 suggest considerable differences between the several options. However, when ozone-aggravated asthma admissions are compared to total asthma admissions (rows 5 and 6), the differences between the various options are small.

The results in Table 4 also raise questions concerning the reasonableness of the assumption of a linear relationship between admissions and ozone concentrations with no threshold concentration. If New York City was just meeting the present NAAQS of 0.12 ppm (1H1EX 0.12), Table 4 indicates that ozone would be responsible for 890 admissions per year. However, of that 890, only 210 admissions would be due to ozone concentrations above the summer background concentration which is taken here to be 0.04 ppm. The majority, 680, or 76.4% of the admissions are attributable to ozone exposure when the ozone concentrations were less than or equal to the summertime background.

Nevertheless, the CASAC Panel could see no "bright line" to use as a guide in selecting the numerical value of an NAAQS. However, some of the members did express personal preferences for the level of the 8-hour NAAQS and they are given below. All the members recommended that there be multiple allowable exceedances. Two other members said that the selection of a level is strictly a policy decision since the risk assessment did not show that any of the NAAQS considered were more protective of public health.

No. of Members	Preference
1	0.09-0.10
3	0.09
1	0.08-0.09
3	0.08
2	policy call

PERSPECTIVE ON OZONE

Let us examine the individual recommendations of the panel members. Of the 15 panel members, ten expressed an opinion on the level of the primary NAAQS. Of the five members who did not express an opinion, four were plant biologists who were on the panel for their expertise regarding the secondary NAAQS issue and they were not expected to comment on the primary NAAQS. A fifth panelist, an atmospheric scientist, gave the panel guidance on atmospheric issues but chose not to participate in the health effects discussions.

Of the ten who voiced an opinion, all endorsed an 8-hour standard and all endorsed multiple exceedances. Three members recommended 0.08 ppm which is clearly *more* stringent than the present NAAQS. Three other members recommended 0.09 ppm and one member recommended a range of 0.09 to 0.10 ppm which, with multiple allowable exceedances, ranges from a NAAQS *equal* in stringency to the current NAAQS to a NAAQS *less* stringent to the current NAAQS. Two other members (including the author) said it is a policy decision because the science has not shown any of the alternatives that are being considered as being more pro-

tective of public health than any other. The last member supported a NAAQS in the "higher end, the middle to higher end."

THE PM REVIEW PROCESS

The major steps in the PM NAAQS review process are illustrated in Table 5. EPA began drafting the PM Criteria Document⁹, in the middle of 1994. Recent Criteria Documents have become mammoth undertakings. The first PM Criteria Document,¹⁰ published in 1969, summarized the relevant science in 220 pages. The final version of the present Criteria Document is a three volume set containing over 2400 pages.

The Staff Paper¹¹ (Staff Paper) contains the Agency's recommendations for the range and form of the NAAQS along with justifications that are drawn from material contained in the Criteria Document. In the past, the CASAC review of a Criteria Document was completed before the Staff Paper was written so that the Staff Paper would reflect the science contained in the final Criteria Document (an exception to this was the recent ozone review¹). The reviews of both the Criteria Document and Staff Paper are iterative processes that usually involve two to three revisions to both of the documents before CASAC reaches closure, and, in the past, the entire process took several years to complete. However, this review was on an accelerated schedule because of a court order resulting from a lawsuit filed by the American Lung Association (ALA).

In February 1994, the ALA filed a suit to compel EPA to complete the PM review by December 1995. The U.S. District Court for the District of Arizona¹² subsequently ordered EPA to complete its review and propose any revision in the Federal Register by June 30, 1996 with final promulgation by January 31, 1997. In addition, the Court adopted EPA's projection that the CASAC review of the Criteria Document should be completed by the end of August 1995. Further, the Court ordered EPA to complete a first draft of the Staff Paper by June 1995 and gave CASAC 3 months to complete its review of the Staff Paper. In addition, the Court stated: "The Court excludes from its revised schedule, the EPA's provisions for interim CASAC review of various Criteria Document and Staff Paper drafts, including participation by CASAC in the development of methodologies for assessment of exposure/risk analyses." As you will see below, however, the review did deviate somewhat from this schedule.

The CASAC Panel members met to discuss the draft of the Criteria Document on August 31, 1995, but they could not come to closure. The panel felt that the Criteria Document required extensive revisions and recommended that it be given the opportunity to review the revised draft.¹³ As a result, both EPA and the ALA petitioned the Court and were granted an extension allowing CASAC until January 5, 1996 to complete its review of the Criteria Document and Staff Paper. CASAC met again on December 14-15, 1995 to review the revised draft of the Criteria Document and the first draft of the Staff Paper. Again the Panel concluded that the Criteria Document did "not provide an adequate review of the available scientific data and relevant studies of PM," and could not come to closure on either the Criteria Document or the Staff Paper.¹⁴ Again, both EPA and the ALA petitioned the Court and were granted an extension allowing CASAC until March 15, 1996 to complete its review of the Criteria Document and June 15, 1996 to complete its review of a revised Staff Paper. At a February 29, 1996, the CASAC Panel succumbed to the pressures exerted by the accelerated schedule and reluctantly came to closure on the Criteria Document. I say reluctantly because in the closure letters it was stated that "a number of members have expressed concern that since we are closing on the Criteria Document before we will be able to see the revised version, we have no assurance that our comments will be incorporated." Nevertheless, the Panel closed on the Criteria Document on March 15, 1996.

On May 16 and 17, the Panel met for the final time to review the revised Staff Paper, and came to closure¹⁶. The details of this review and the CASAC recommendations will be discussed shortly.

HISTORY OF THE PM STANDARDS

The history of the PM standards is summarized in Table 6. In 1971, EPA set annual average and 24-hour NAAQS for total suspended particulates (TSP). Total suspended particulates consisted of any PM that was collected on the filter of a high volume sampler operating within certain EPA specifications. The upper size captured by the high volume sampler varied with wind speed and wind direction but was generally limited to PM with diameters less than 40 μm (the width of a human hair is about 70 μm). Between 1971 and 1987, it was realized that the most important PM, from a health perspective, were those that deposited in the deep lung

(tracheobronchial or pulmonary) region of the of the respiratory system. Maximum PM penetration to the deep lung region occurs during oronasal (combined nose/mouth breathing) or mouth breathing and deposition is restricted to those PM equal to or less than 10 μm in diameter. In nasal breathing, deep lung deposition is limited to particles less than or equal to about 1 μm in diameter. Consequently, in 1987, EPA replaced the TSP NAAQS with 24-hour and annual PM_{10} NAAQS where PM_{10} refers to those particles that are equal to or less than 10 μm in diameter. Operationally PM_{10} is defined by the Federal Reference method and sampler. In terms of sampler collection efficiency, the 10 μm cut point represents the size of the particle that is collected with a 50% collection efficiency.

The PM NAAQS is the only NAAQS that is not chemically specific although it is understood that the toxicity of individual particles are not equal. Furthermore, it is understood that the potential for biological responses varies with particle size. As mentioned above, for normal nasal breathing, the particle sizes of concern are generally 1 μm in diameter or less, while for oronasal breathing, particles equal to or less than 10 μm in diameter are of concern. In addition, the sources of the fine particles ($\text{PM}_{1.0}$ or $\text{PM}_{2.5}$) are generally different from the sources of the coarser particles (particles greater than or equal to 2.5 μm in diameter. For example particles less than 2.5 μm in diameter are formed primarily by combustion or secondary chemical reactions in the atmosphere whereas particles greater than or equal to 2.5 μm in diameter are formed primarily by mechanical processes (construction, demolition, unpaved roads, wind erosion, etc.) For these reasons, many have felt that fine and coarse particles should be treated as separate pollutants because different control strategies are required to address both size ranges. This logic and the health effects discussed below are what lead EPA staff to recommend the separate $\text{PM}_{2.5}$ and PM_{10} NAAQS listed in Table 6.

The proposed $\text{PM}_{2.5}$ NAAQS is considerably more stringent than the existing PM_{10} NAAQS. Based on 1993–95 PM_{10} data, there are 41 U.S. counties with monitors not meeting either the annual or 24-hr PM_{10} NAAQS. Under the new $\text{PM}_{2.5}$ NAAQS proposals, it is estimated that the nonattainment counties would be about 170. However, there are two caveats. First, very few places have $\text{PM}_{2.5}$ monitors. Consequently $\text{PM}_{2.5}$ data are estimated. The $\text{PM}_{2.5}$ concentrations were estimated for all counties with PM_{10} samplers by multiplying the relatively abundant PM_{10} data by ratios derived from a much more limited $\text{PM}_{2.5}/\text{PM}_{10}$ data base. Second, these estimates only include counties with PM_{10} monitors. It is likely, that there will be significant numbers of counties currently without monitors that will eventually be found to be out of attainment. As a consequence, the actual number of PM nonattainment areas will be substantially higher than EPA's estimates.

PM HEALTH EFFECT STUDIES: RESULTS AND IMPLICATIONS

Although individual PM health effect studies have focused on a variety of endpoints, for obvious reasons the epidemiology studies that focused on human mortality were the primary focus of this review. Consequently, we will only discuss these studies.

There were two types of PM-mortality studies cited by EPA. The first were the short-term, acute mortality studies which compared the daily PM and mortality time series in a dozen or so locations around the US. After filtering out or accounting for the effects of such things as seasonality, day of the week, meteorology, etc. on mortality, the remaining statistical relationship between daily PM and daily mortality was quantified. Although this relationship varied from location to location, the average value was a 4% increase in daily deaths for a 50 $\mu\text{g}/\text{m}^3$ increase in PM_{10} concentrations.

The second type of epidemiological study is the long-term prospective cohort studies where the health status of certain groups (cohorts) of individuals is followed for a number of years in various locations around the country. In these studies, the annual mortality rate in a given location is related to the annual average PM_{10} or $\text{PM}_{2.5}$ concentrations after the mortality rates have been adjusted for smoking and some other potential confounding variables. Of the three studies reported in the literature, two show a positive relationship between annual mortality and PM and attribute two to three times the number of deaths to PM as the short-term acute effect studies. The third study shows no PM-mortality relationship but EPA dismissed this study for a number of reasons including its lower statistical power (smaller sample size). EPA uses higher mortality estimates from the two studies to conclude that there are premature deaths due to chronic exposure to PM in addition to the deaths due to acute exposures identified in the time-series studies.

In addition, EPA also concluded that the mortality was due to $PM_{2.5}$ rather than the coarse fraction of the PM_{10} . As will be discussed below, the evidence for this conclusion was ambiguous.

CASAC'S INTERPRETATION AND RECOMMENDATIONS ON PM

Table 4 summarizes the Panel members' recommendations concerning the forms and levels of the primary standards. Although some Panel members preferred to have a direct measurement of coarse mode PM ($PM_{10-2.5}$) rather than using PM_{10} as a surrogate for it, there was a consensus that retaining an annual PM_{10} NAAQS at the current level is reasonable at this time. A majority of the members recommended keeping the present 24-hour PM_{10} NAAQS, although those commenting on the form of the standard strongly recommended that the form be changed to one that is more robust than the current standard to provide some insulation from the impacts of extreme meteorological events. Because of the acceptance that $PM_{10-2.5}$ and $PM_{2.5}$ are different pollutants, there was also a consensus that a new $PM_{2.5}$ NAAQS be established, with 19 Panel members endorsing the concept of a 24-hour and/or an annual $PM_{2.5}$ NAAQS. The remaining two Panel members did not think any $PM_{2.5}$ NAAQS was justified. However, as indicated in Table 4, there was no consensus on the level, averaging time, or form of a $PM_{2.5}$ NAAQS. At first examination of Table 4, the diversity of opinion is obvious and appears to defy further characterization. However, the opinions can be classified into several broad categories. Four Panel members supported specific ranges or levels within or toward the lower end of EPA staff's recommended ranges. Seven Panel members supported specific ranges or levels near, at, or above the upper end of staff's recommended ranges. Two members did not think a $PM_{2.5}$ NAAQS was warranted at all. The remaining eight other Panel members endorsed the concept of a $PM_{2.5}$ NAAQS, but declined to select a specific range or level. Consequently, only a minority of the Panel members supported a range that includes the present EPA proposals.

However, most of the members who declined to recommend a range had caveats which appear as footnotes in Table 7. The caveats include: "recommends a more robust 24-hr. form," "concerned upper range is too low based on national $PM_{2.5}/PM_{10}$ ratio," "leans towards high end of EPA's proposed range," "yes, but decision not based on epidemiological studies," "low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have $PM_{2.5}$ pollution problems," "only if EPA has confidence that reducing $PM_{2.5}$ will indeed reduce the components of particles responsible for their adverse effects," and "concerned lower end of range is too close to background."

The diversity of opinion expressed by the Panel members reflected the many unanswered questions and large uncertainties associated with establishing causality of the association between $PM_{2.5}$ and mortality. Most Panel members were influenced, to varying degrees by these unanswered questions and uncertainties. The concerns include but are not limited to: (1) the influence of confounding variables, (2) measurement errors, (3) the existence of possible alternative explanations, (4) the lack of an understanding of toxicological mechanisms, (5) the fraction of the daily mortality that is advanced by a few days because of pollution, (6) exposure misclassification, (7) the shape of the dose-response function, and (8) the use of different models in all the studies. Let me expand on these issues.

The first three concerns are related because they pertain to how certain we are that we have identified the correct causative agent. As mentioned earlier, PM_{10} and $PM_{2.5}$ are not single chemical entities. They are composed of four or five major constituents and hundreds of trace constituents. Some have suggested that the causative agent could be some constituent of the PM rather than the total PM or total $PM_{2.5}$ which would require a control strategy targeted at the causative constituent rather than at PM_{10} or $PM_{2.5}$ in general. Also because many of the PM constituents are highly correlated (also with some of the gaseous pollutants as well), the regression methodologies used to determine association, tend to select those variable with the smallest measurement error. For example, $PM_{2.5}$ and PM_{10} are measured much more precisely than the coarse fraction of the PM_{10} ($PM_{10-2.5}$). Consequently, the slightly higher relative risk calculated from the statistical models for $PM_{2.5}$ (versus $PM_{10-2.5}$) is not proof that $PM_{10-2.5}$ is not the causative agent. Finally, several studies including some of the recent reanalyses of original studies have included gaseous criteria pollutants in their model and discovered that in many cases ozone, sulfur dioxide or carbon monoxide can be as important, and in some cases, more important than PM in describing the mortality. When the data bases are segregated by season, even more confusing results occur as different pollutants are identified for each season as being the apparent causative agent. This has led some to conclude that it

is overall air pollution that is causing the excess mortality and that PM is just a surrogate measure. If that is the case, it does not necessarily follow that reducing the concentrations of a surrogate will result in reduced mortality.

The fourth issue of concern has caused several of the Panel members, including one of the chest physicians to state that there is no biologically plausible mechanism that could explain the apparent relationship between acute mortality and PM at concentrations that are a fraction of the present PM₁₀ NAAQS. This has led some to postulate that the acute mortality is actually a "harvesting" effect. That is, individuals who are terminally ill die somewhat prematurely due to the additional stress caused by PM or overall air pollution. While this may explain some or most of the acute deaths, it can not explain the apparent long-term, chronic deaths attributed to annual PM concentrations in the prospective cohort studies. These prospective cohort studies suggest that the acute mortality only account for about a third to a half of the total deaths attributed to PM. However, all or most of this discrepancy vanishes when additional potentially confounding variables are included in the cohort studies and historical or cumulative rather than concurrent air pollution exposures are considered.

The exposure misclassification concern revolves around the validity of the assumption made in all of the acute studies that daily ambient PM data collected from a centrally located air monitoring site is representative of personal exposure to PM. Results from studies which examined this assumption are ambiguous. The shape of the dose-response function is also a concern. Because of measurement errors, the present statistical methodologies are incapable of detecting the existence of a possible threshold concentration below which acute mortality would not occur. Finally, there is some concern because the statistical models used in the various geographical areas are different. At different sites, different combinations of variables, averaging times, methods for accounting for seasonality and meteorology, and lag times have been used to produce the reported PM-mortality relationships.

The lack of consensus on many of these issues can be partially attributed to the accelerated review schedule. The deadlines did not allow adequate time to analyze, integrate, interpret, and debate the available data on this very complex issue. Nor did the court-ordered schedule recognize that achieving the goal of a scientifically defensible NAAQS for PM may require iterative steps to be taken in which new data are acquired to fill obvious and critical voids in our knowledge. The previous PM NAAQS review took 8 years to complete.

The Panel was unanimous, however, in its desire to avoid a similar situation when the next PM NAAQS review cycle is under way by a future CASAC Panel. CASAC strongly recommended that EPA immediately implement a targeted research program to address these unanswered questions and uncertainties. It is also essential that long-term PM_{2.5} measurements are obtained. CASAC volunteered to assist EPA in the development of a comprehensive research plan that will address the questions which need answers before the next PM review cycle is completed.

PERSPECTIVE

Since PM₁₀ measurements became widespread in 1988, significant and continuous declines in ambient PM₁₀ concentrations have been observed throughout the U.S. Nationwide PM₁₀ concentrations have declined 22% from 1988 to 1995.¹⁷ The reason for this decline is because of the implementation of existing control programs required by the 1990 Clean Air Act Amendments that target PM_{2.5} precursors (VOCs, NO_x, and SO₂), diesel PM emissions and other primary emission sources. This trend will continue for the foreseeable future as additional measures required by the Amendments are phased in. Consequently, there is time to conduct the research recommended by CASAC which targets the concerns discussed above. Then appropriate PM_{2.5} NAAQS could be established.

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¹⁴Wolff, G.T. "Clean Air Scientific Advisory Committee (CASAC) Comments on the November 1995 Drafts of the Air Quality Criteria for Particulate Matter and the Review of National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information (OAQPS Staff Paper)," EPA-SAB-CASAC-LTR-96-003, U.S. EPA, Washington, DC, January 5, 1996.

¹⁵Wolff, G.T. "Closure by the Clear Air Scientific Advisory Committee (CASAC) on the Draft Air Quality Criteria for Particulate Matter," EPA-SAB-CASAC-LTR-96-005, U.S. EPA, Washington, DC, March 15, 1996.

¹⁶Wolff, G.T. "Closure by the Clean Air Scientific Advisory Committee (CASAC) on the Staff Paper for Particulate Matter," EPA-SAB-CASAC-LTR-96-008, U.S. EPA, Washington, DC, June 13, 1996.

¹⁷U.S. EPA Office of Air Quality Planning and Standards. "Air Quality Trends," EPA454/F-95-003, U.S. EPA, Research Triangle Park, NC, September, 1995.

**Table 1: Steps in the NAAQS review process.
Completion dates are for the ozone review**

	Steps in a NAAQS Review	Completion Date
1	CASAC review of the Criteria Document	June 1994 to September 1995
2	CASAC closure on Criteria Document	November 28, 1995
3	CASAC review of Staff Paper	February 1995 to September, 1995
4	CASAC closure on Staff Paper	November 30, 1995
5	EPA publishes proposed NAAQS in Federal Register	December 13, 1996
6	EPA promulgates final NAAQS in Federal Register	June 28, 1997

Table 2: Historical Overview of Ozone NAAQS

Year	Primary NAAQS	Secondary NAAQS
1971	1-hr. @ 0.08 ppm	same as primary
1977	1-hr. @ 0.12 ppm 3 ex in 3 years	same as primary
1993	reaffirmed 1977 NAAQS	reaffirmed 1977 NAAQS
1996 (recommended in Staff Paper)	8-hr. @ 0.07-0.09 ppm 1 to 5 ex per year averaged over 3 years **	3 month SUM06 25-36 ppm-hours [#]
December 13, 1996 proposal	8-hr @ 0.08 ave of 3rd highest in 3 yrs	either equal to primary or 3-mo SUM06 @ 25 ppm-hours

³ exceedances allowed within 3 consecutive years

** 1 to 5 exceedances allowed within a year averaged over a 3-year period

[#] see Criteria Document⁵ for an explanation

Table 3: Range of Median Percent of Outdoor Children Responding Across Nine U.S. Urban Areas Upon Attaining Alternative Air Quality Standards.^a

Health Endpoints	Range of Median Risk Estimates Associated With Just Attaining Alternative Standards (percent of outdoor children responding)										
	Alternative 1-Hour NAAQS		1 Expected Exceedance Standards					5 Expected Exceedance Standard			
	1H1EX ^b 0.12 ppm 5-14	1H1EX 0.10 ppm 3-9	8H1EX 0.10 ppm 7-16	8H1EX 0.09 ppm 5-12	8H1EX 0.08 ppm 3-8	8H1EX 0.07 ppm 2-5	8H1EX 0.09 ppm 5-14	8H1EX 0.08 ppm 3-10	8H1EX 0.07 ppm 2-5	8H1EX 0.09 ppm 5-14	8H1EX 0.08 ppm 3-10
FEV ₁ decrement ≥ 15%	1-6	0-4	2-7	2-5	1-3	0-1	2-6	1-4			
FEV ₁ decrement ≥ 20%	0	0	0-1	0	0	0	-	-			
Moderate or Severe Pain on Deep Inspiration	0-1	0	0-1	0-1	0	0	-	-			
Moderate or Severe Cough											

^a Estimates for alternative NAAQSs with 1 exceedance from Table V-18 in final Staff Paper^c; estimates for NAAQSs with 5 exceedances from Table VI-1 in August 1995 draft Staff Paper.

^b 1H means 1-hour standard; 1EX means 1 allowable exceedance per year.

Table 4: Estimated Hospital Admissions for Asthmatics in the New York City Area

	IHIE	IHIE	8HIE	8HIE	8HIE	8HIE	8HIE	8HIE	8HIE	8HIE	AS IS
	0.12	0.10	0.10	0.09	0.08	0.07	0.09	0.08	0.09	0.08	
Excess Admissions ^a	207	130	240	180	115	60	180	120	180	120	388
% Δ from present std	70-344	0%	+16%	-13%	-44%	-71%	-13%	-42%	-13%	-42%	+87%
Excess + background ^b	909	810	920	860	804	740	860	797	860	797	1065
% Δ from present standard	308-1509	0%	+1%	-5%	-12%	-19%	-5%	-12%	-5%	-12%	+17%
All Asthma Admissions	14,819	14,742	14,852	14,792	14,727	14,672	14,792	14,732	14,792	14,732	15,000
% Δ from present standard	0%	-0.5%	+0.2%	-0.2%	-0.6%	-1.0%	-0.2%	-0.6%	-0.2%	-0.6%	+1.2%

a - excess asthma admissions attributed to ozone levels exceeding a background concentration of 0.04 ppm; the values with ranges (90% confidence intervals) are from Table V-20 in the Staff Paper⁶; single value estimates are from Figure V-17 in the Staff Paper⁶

b - asthma admissions included in (a) plus those due to background ozone concentrations; admissions due to background = 1065 - 388 = 677

**Table 5: Steps in the NAAQS review process.
Completion dates are for the PM review**

	Steps in a NAAQS Review	Completion Date
1	CASAC review of the Criteria Document	June 1995 to March 1996
2	CASAC closure on Criteria Document	March 15, 1996
3	CASAC review of Staff Paper	November 1995 to June 1996
4	CASAC closure on Staff Paper	June 13, 1996
5	EPA publishes proposed NAAQS in Federal Register	December 13, 1996
6	EPA promulgates final NAAQS in Federal Register	June 28, 1997

Table 6: Historical Overview of PM NAAQs

YEAR	MEASURE	24-HR ($\mu\text{g}/\text{m}^3$)	ANNUAL ($\mu\text{g}/\text{m}^3$)
1971	total suspended particulates (TSP)	260	75
1987	PM ₁₀ (particulates with diameters $\leq 10 \mu\text{m}$)	150	50
1996	<i>EPA Staff recommendation:</i>		
	PM _{2.5}	18-65	12.5-20
	PM ₁₀	150	40-50
12/96	<i>Federal Register Notice</i>		
	PM _{2.5}	50	15
	PM ₁₀	150	50

Table 7: Summary of CASAC Panel Members Recommendations
(all units $\mu\text{g}/\text{m}^3$)

	PM _{2.5}	PM _{2.5}	PM ₁₀	PM ₁₀
	24-hr	Annual	24-hr	Annual
EPA Staff Recommendation	18 -65	12.5 - 20	150 ¹³	40 - 50
December, 1996 Proposal	50	15	150	50
Discipline of Panel Member				
Epidemiologist ¹	20 - 50	no	no	40 - 50
Epidemiologist	20 - 30	15 - 20	no	50
Health Effects Expert	20 - 50 ³	15 - 20	no	40 - 50
Atmospheric Scientist	20 - 50 ³	20 - 30	no	40 - 50 ⁴
Biologist	yes ²	yes ²	150	50
Chest Physician	yes ²	yes ²	150	50
Atmospheric Scientist	yes ^{2,3,12}	yes ^{2,3}	150 ^{3,13}	50
Atmospheric Scientist	yes ^{2,9}	yes ^{2,9}	yes ⁴	yes ⁴
Atmospheric Scientist	yes ^{1,10}	yes ¹⁰	no ^{3,4}	yes ⁴
Epidemiologist ¹	yes ^{2,11}	no	150	yes ²
Atmospheric Scientist	yes ³	no	150 ¹³	50
Atmospheric Scientist	yes ^{2,3,6,12}	yes ^{2,3,6}	no	yes ⁴
Toxicologist	50	20	150	50
Atmospheric Scientist	no	20	150	50
Statistics Expert	no	25-30 ⁷	no	yes ²
Chest Physician	≥65	no	150	50
Epidemiologist	75 ⁷	25-30 ⁷	150	50
Biologist	≥ 75	no	150	40 - 50
Atmospheric Scientist	≥75 ^{3,7}	no	150 ³	50
Toxicologist	no ⁸	no ⁸	150	50
Toxicologist	no	no	150	50

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM_{0.25} standard rather than a PM₁₀ standard

⁵ concerned upper range is too low based on national PM_{2.5}/PM₁₀ ratio

⁶ leans towards high end of EPA's proposed range

⁷ desires equivalent stringency as present PM₁₀ standards

⁸ if EPA decides a PM_{2.5} NAAQS is required, the 24-hr. and annual standards should be 75 and 25 $\mu\text{g}/\text{m}^3$, respectively with a robust form

⁹ yes, but decision not based on epidemiological studies

¹⁰ low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have PM_{2.5} pollution problems

¹¹ only if EPA has confidence that reducing PM_{2.5} will indeed reduce the components of particles responsible for their adverse effects

¹² concerned lower end of range is too close to background

¹³ the annual standard may be sufficient; 24-hour level recommended if 24-hour NAAQS is retained
• the chair's recommendation

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, DC, November 30, 1995.

EPA-SAB-CASAC-LTR-96-002

Hon. CAROL M. BROWNER, *Administrator*,
U.S. Environmental Protection Agency,
401 M. Street, SW., Washington, DC 20460.

RE: CASAC Closure on the Primary Standard Portion of the Staff Paper for Ozone

Dear Ms. Browner: A Panel of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB) met on March 22, 1995, to review a draft of the primary standard part of the document entitled *Review of National Ambient Air Quality Standards for Ozone Assessment of Scientific and Technical Information* OAQPS Staff Paper. At that time, a draft of the secondary standard portion of the document was not completed. At the March meeting, the Panel made extensive recommendations for strengthening the document. In August 1995, a revised Staff Paper, which included a first draft of the secondary standard portion was sent to CASAC panel members for review. On September 19 and 20, 1995, the Panel met to complete this review. The Panel members' comments reflect their satisfaction with the improvements made in the scientific quality and completeness of the primary standard portion of the Staff Paper. The changes made in that portion of the document are consistent with CASAC's recommendations. However, the Panel Members provided additional comments to your staff at the meeting and subsequently in writing. Although the Panel would like to have these comments considered for incorporation in the Staff Paper, the Panel did not feel that it was necessary to review another revised version and came to closure on the primary standard portion. It was the consensus of the Panel that although our understanding of the health effects of ozone is far from complete, the document provides an adequate scientific basis for making regulatory decisions concerning a primary ozone standard.

The Panel could not come to closure, however, on the secondary standard portion of the Staff Paper which was a first draft. To facilitate further development of this part of the Staff Paper, the Panel members have provided detailed comments to your staff. The Panel felt that the suggested revisions were extensive enough to warrant a review of the next draft.

I would like to summarize for you the Panel's recommendations concerning the primary standard. It was the consensus of the Panel that EPA's selection of ozone as the surrogate for controlling photochemical oxidants is correct. It was also the consensus of the Panel that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard. The Panel was in unanimous agreement that the present 1-hour standard be eliminated and replaced with an 8-hour standard.

The Panel felt that the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations. Based on information now available, it appears that ozone may elicit a continuum of biological responses down to background concentrations. This means that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an "adequate margin of safety" is no longer possible. It further means that EPA's risk assessments must play a central role in identifying an appropriate level.

To conduct the risk assessments, the Agency had to identify the population at risk and the physiological responses of concern, develop a model to estimate the exposure of this population to ozone, and develop a model to estimate the probability of an adverse physiological response to the exposure. The Panel agrees with EPA that the selection of "outdoor children" and "outdoor workers," particularly those with pre-existing respiratory disease are the appropriate populations with the highest risks. After considerable debate, it was the consensus of the Panel that the Agency's criteria for the determination of an adverse physiological response was reasonable. Nevertheless, there was considerable concern that the criteria for grading physiological and clinical responses to ozone was confusing if not misleading. The Panel concurs with the Agency that the models selected to estimate exposure and risk are appropriate models. However, because of the myriad of assumptions that are made to estimate population exposure and risk, large uncertainties exist in these estimates.

The results of two of the risk analyses are presented in Tables VI-1 and VI-2 in the Staff Paper and are reproduced in the attached tables. The ranges of the risk estimates across nine cities for outdoor children are presented in Table VI-1. Because of the large number of stochastic variables used in the exposure models, the

exposure estimates vary from run to run. However, the ranges are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates.

The single estimates presented in Table VI-2 do not reflect any of the uncertainties associated with these estimates. (Table VI-2 contains only the estimated hospital admissions due to asthma which account for over 85 percent of the estimated total hospital admissions due to ozone exposure). These uncertainties need to be explicitly articulated in order to put the estimates in proper perspective. Nevertheless, based on the results presented in these and other similar tables presented in the Staff Paper, the Panel concluded that there is no "bright line" which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of public health. For example, the differences in the percent of outdoor children (Table VI-1) responding between the present standard and the most stringent proposal (8H1EX at 0.07 ppm) are small and their ranges overlap for all health endpoints. In Table VI-2, the estimates in row 1, which appeared in the draft Staff Paper, suggest considerable differences between the several options. However, when ozone-aggravated asthma admissions are compared to total asthma admissions (rows 5 and 6), the differences between the various options are small. Consequently, the selection of a specific level and number of allowable exceedences is a policy judgment. Although it was the consensus of the Panel that the ranges of concentrations and allowable exceedences proposed by the Agency were appropriate, a number of Panel members expressed "personal" preferences for the level and number of allowable exceedences. Of the ten panel members who expressed their opinions, all ten favored multiple allowable exceedences, three favored a level of 0.08 ppm, one favored the mid to upper range (0.08-0.09 ppm), three favored the upper range (0.09 ppm), one favored a 0.009-0.10 ppm range with health advisories issued when the 8-hour ozone concentration was forecasted to exceed 0.007 ppm, and two just endorsed the range presented by the Agency as appropriate and stated that the selection should be a policy decision. The members who favored the low numbers expressed concern over the evidence for chronic deep lung inflammation from the controlled human and animal exposure studies and the observations of pain on deep inspiration in some subjects.

Because there is no apparent threshold for responses and no "bright line" in the risk assessment, a number of panel members recommended that an expanded air pollution warning system be initiated so that sensitive individuals can take appropriate "exposure avoidance" behavior. Since many areas of the country already have an infrastructure in place to designate "ozone action days" when voluntary emission reduction measures are put in place, this idea may be fairly easy to implement.

It was also the consensus of the Panel that the form of the 8-hour standard be more robust than the present 1-hour standard. The present standard is based on an extreme value statistic which is significantly dependent on stochastic processes such as extreme meteorological conditions. The result is that areas which are near attainment will randomly flip in and out of compliance. A more robust, concentration-based form will minimize the "flip-flops," and provide some insulation from the impacts of extreme meteorological events. The Panel also endorses the staff recommendation for creating a "too close to call" category.

Since the last ozone NAAQS review, the scientific community has made great strides in their understanding of the health effects of ozone exposure because of ongoing research programs. Panel members were very impressed with how much more we understand now as compared to the prior round. Nevertheless, there are still many gaps in our knowledge and large uncertainties in many of the assessments. For example, there is little information available on the frequency of human activity patterns involving outdoor physical exercise. Little is also known about the possible chronic health impacts of ozone exposure over a period of many years. In addition, there is no clear understanding of the significance of the inflammatory response inferred from the broncholavage data. Panel members stated, however, that the scientific community is now in a position to frame the questions that need to be better resolved so the uncertainties can be reduced before the next ozone review in 5 years. For this reason, it is important that research efforts on the health and ecological effects of ozone not be reduced because we have come to closure on this review.

CASAC would appreciate being kept informed of progress on establishing a revised or new ozone standard, and plans for research on ozone effects. Please do not hesitate to contact me if CASAC can be of further assistance in this matter. We look forward to receiving the revisions of the secondary standard portion of the Staff Paper.

Sincerely,

DR. GEORGE T. WOLFF,
Chair, Clean Air Scientific Advisory Committee.

RESPONSE OF DR. WOLFF TO AN ADDITIONAL QUESTION FROM SENATOR HUTCHINSON

Question. Dr. Wolff, please explain the differences between your recommendation for a PM standard and the EPA's proposed standard?

Response. The decision to propose a PM_{2.5} is consistent with the advice CASAC gave to EPA. However, CASAC panel members could come to no consensus on the appropriate ranges or levels for PM_{2.5} standards.

The 21 members of the CASAC PM review panel expressed a tremendous diversity of opinion and this is documented in the attached Table that is reproduced from CASAC's closure report that was sent to the EPA Administrator. The Table was also included in my written comments to the Subcommittee. Pertaining to the 24-hour PM_{2.5} NAAQS, only five members recommended a range which included 50 µg/m³ or lower. Four members recommended greater than or equal to the top of EPA's range. Four members did not recommend a 24-hour NAAQS. The remaining seven members merely endorsed the concept of a 24-hour PM_{2.5} NAAQS, but declined to select a value or range. Also note from the Table that the diversity of opinion was exhibited by the health experts as well as the non-health experts. Clearly, this is not an endorsement of a 50 µg/m³ standard.

For the annual standard, only two members favored a range that went as low as 15 µg/m³. Two members favored 20 µg/m³; one chose 20-30 µg/m³; two chose 25-30 µg/m³; and eight did not think an annual PM_{2.5} NAAQS was needed. The remaining six members merely endorsed the concept of an annual standard but declined to select a value or range. This is not an endorsement of an annual PM_{2.5} NAAQS of 15 µg/m³.

Wolff's Response to Senator Hutchinson

Table - Summary of CASAC Panel Members Recommendations
(all units $\mu\text{g}/\text{m}^3$)

	PM _{2.5}	PM _{2.5}	PM ₁₀	PM ₁₀
	24-hr	Annual	24-hr	Annual
EPA Staff Recommendation	18 -65	12.5 - 20	150 ¹³	40 - 50
Discipline of Panel Member				
Epidemiologist ¹	20 - 50	no	no	40 - 50
Epidemiologist	20 - 30	15 - 20	no	50
Health Effects Expert	20 - 50 ³	15 - 20	no	40 - 50
Atmospheric Scientist	20 - 50 ³	20 - 30	no	40 - 50 ⁴
Biologist	yes ²	yes ²	150	50
Chest Physician	yes ²	yes ²	150	50
Atmospheric Scientist	yes ^{2,3,12}	yes ^{2,3}	150 ^{2,13}	50
Atmospheric Scientist	yes ^{2,9}	yes ^{2,9}	yes ⁴	yes ⁴
Atmospheric Scientist	yes ^{3,10}	yes ¹⁰	no ^{3,4}	yes ⁴
Epidemiologist ¹	yes ^{2,11}	no	150	yes ²
Atmospheric Scientist	yes ^{3,5}	no	150 ¹³	50
Atmospheric Scientist	yes ^{2,3,6,12}	yes ^{2,5,6}	no	yes ⁴
Toxicologist	50	20	150	50
Atmospheric Scientist	no	20	150	50
Statistics Expert	no	25-30 ⁷	no	yes ²
Chest Physician	≥65	no	150	50
Epidemiologist	75 ⁷	25-30 ⁷	150	50
Biologist	≥75	no	150	40 - 50
Atmospheric Scientist ⁹	≥75 ^{2,7}	no	150 ³	50
Toxicologist	no ⁸	no ⁸	150	50
Toxicologist	no	no	150	50

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM_{10-2.5} standard rather than a PM₁₀ standard

⁵ concerned upper range is too low based on national PM_{2.5}/PM₁₀ ratio

⁶ leans towards high end of EPA's proposed range

⁷ desires equivalent stringency as present PM₁₀ standards

⁸ if EPA decides a PM_{2.5} NAAQS is required, the 24-hr. and annual standards should be 75 and 25 $\mu\text{g}/\text{m}^3$, respectively with a robust form

⁹ yes, but decision not based on epidemiological studies

¹⁰ low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have PM_{2.5} pollution problems

¹¹ only if EPA has confidence that reducing PM_{2.5} will indeed reduce the components of particles responsible for their adverse effects

¹² concerned lower end of range is too close to background

¹³ the annual standard may be sufficient; 24-hour level recommended if 24-hour NAAQS is retained

¹⁴ George Wolff's recommendation

RESPONSES BY DR. WOLFF TO ADDITIONAL QUESTIONS FROM SENATOR BOXER

Question 1a. After its review of the science, did CASAC make a determination that there is an adequate scientific basis for the Administrator to revise the standards?

Response. No. CASAC's closure on the Staff Papers simply means that the Panels felt that the documents provided an adequate scientific basis for making regulatory decisions concerning standards. For ozone, the Panel concluded: "there is no 'bright line' which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of public health." For PM_{2.5}, there was no agreement among the Panel members on the level or form of the standard.

Question 1b. For both ozone and particulates, did CASAC approve the EPA documents and the recommended specific ranges for new more stringent standards?

Response. CASAC came to closure on both Criteria Documents and Staff Papers. Closure on a Criteria Document simply means that CASAC is satisfied that the document provides an adequate review of the available scientific data and relevant studies. Closure on the Staff Papers means that CASAC is satisfied that the document will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning the standards. It is not an endorsement of EPA's recommendations or the arguments used by EPA to support their recommendations.

For ozone, the Panel did not recommend a more stringent standard. "It was the consensus of the Panel that the ranges of concentrations and allowable exceedences proposed by the Agency were appropriate," but this is not an endorsement for a "more stringent standard" because the range includes 0.09 ppm with five allowable exceedences which is *less stringent* than the present 1-hour standard.

For PM, CASAC did *not* endorse EPA's recommended range. The 21 members of the CASAC PM review panel expressed a tremendous diversity of opinion and this is documented in the attached Table that is reproduced from CASAC's closure report. The Table was also included in my written comments to the Subcommittee. Pertaining to the 24-hour PM_{2.5} NAAQS, only five members recommended a range that was within EPA's recommended range. Four members recommended greater than or equal to the top of EPA's range. Four members did not recommend a 24-hour NAAQS. The remaining seven members merely endorsed the concept of a 24-hour PM_{2.5} NAAQS, but declined to select a value or range (see footnote 2 in the Table). Also note from the Table that the diversity of opinion was exhibited by the health experts as well as the non-health experts. Clearly, this was not an endorsement of EPA's recommended range.

For the annual standard, four members favored a range or value that was within EPA's recommended range. Three members favored a higher range and eight did not think an annual PM_{2.5} NAAQS was needed. The remaining six members merely endorsed the concept of an annual standard but declined to select a value or range. Again, note from the Table that the diversity of opinion was exhibited by the health experts as well as the non-health experts. Clearly, this also was not an endorsement of EPA's recommended range.

Question 1c. Did CASAC unanimously support moving to an 8-hour standard for ozone?

Response. Yes, but this is not an endorsement of a more stringent standard.

Question 1d. Did 19 of 21 CASAC members support moving to a fine particulate standard for particulates?

Response. Yes, but there was no agreement on the level or the form of the standard. Those who recommended a level near, at, or above EPA's recommended range did so as a means of distinguishing between coarse and fine particles in order to facilitate research and data collection.

Question 2. Scientific studies show that healthy adults can suffer a temporary loss of lung function of 20 to 60 percent if they exercise outside during summer months. In face of this evidence, industry representatives claim this is not a health effect because it is a temporary and reversible effect. What in your personal view, is a health effect?

Response. The ozone Staff Paper closure letter on page 2 states: "After considerable debate, it was the consensus of the Panel that the Agency's criteria for the determination of an adverse physiological response was reasonable." For the FEV_{1.0} lung function test referred to in the question, the criteria for being adverse were a 20 percent decrease in performance for a healthy individual and a 15 percent performance decrease for anyone with preexisting respiratory illness.

I am not a physician, so I do not have a personal view.

Question 3. Some people have suggested that EPA not make regulatory decisions unless all the raw data that forms the basis of the studies supporting that decision are made publicly available. Why should industry be able to obtain access to data gathered by public health researchers in order to challenge the results, but withhold their own data to public scrutiny?

Response. This is an important issue. There have been a number of studies where researchers have tried to reconstruct the original investigators' results, but since the original investigators' data are unavailable there is no way to be sure the data sets are the same. Nevertheless, these reanalyses show, in general, that the original investigators' results can be replicated only if an identical model and identical assumption are used. Using what the new investigators call equally plausible models and assumptions, the PM/mortality relationship vanishes. Two of these re-analyses by the Health Effects Institute and an EPA-funded study by the National Institute for Statistical Sciences question the validity of a PM/mortality relationship at concentrations below the standard. Therefore it is important for independent investigators to be able to re-analyze original data sets.

In general, most of the data sets can be reasonably reconstructed because the mortality, pollution, and meteorological data are publicly available. One exception to this is the Harvard Six City study which EPA has relied upon heavily.

As far as I am aware, all of the PM epidemiological data bases compiled by industry-funding are available to anyone who requests them.

Question 4a. You spent 20 years working for GM is that correct?

Response. Yes. I spent 16 years as an atmospheric science researcher for General Motors Research Laboratories before becoming chair of CASAC. Prior to that, I was employed by an environmental control agency.

Question 4b. The auto industry has been a major source of air pollution for both vehicles and the automotive plants themselves—is that correct?

Response. Yes.

Question 4c. General Motors and the auto industry have historically opposed emission controls. Over the past 4 years of CASAC's reviews of the clean air standards have you had discussions with anyone in GM or the auto industry about the proposed ozone or PM standards?

Response. GM management and I mutually agreed that I would not participate in GM's or AAMA's discussions and activities regarding the PM and ozone standards.

Question 4d. Do you think GM or the industry would be adversely affected by a revised ozone or PM standard?

Response. If the proposed standards are adopted, states will need to find significant additional emission reductions. All sources that are targeted by a state for additional reductions will likely be adversely affected.

Question 4e. Is it not true that last fall you had a briefing for certain selected reporters on this subject held at the American Automobile Manufacturers Association offices? In that case—were you speaking on behalf of the auto manufacturers or on behalf of CASAC?

Response. As chair of CASAC, the American Automobile Manufacturers Association asked me to brief these reporters on what was in the CASAC closure letters.

Question 5. Do your views and assertions reflect the views of CASAC as a whole?

Response. When asked to speak for CASAC, as I have been at these hearings, I have an obligation to my colleagues on CASAC to portray their views accurately. I try to accurately portray the issues where we reached consensus and accurately portray the diversity of opinion that CASAC expressed on other issues. Consequently, I feel the views and assertions that I make in these presentations do reflect those of the CASAC members.

Question 6. You have said that in the case of ozone, there is no statistically significant difference in public health risk between the current ozone standard (0.12 ppm over a 1-hour period) and the most stringent ozone standard of the range recommended by CASAC (0.07 ppm over an 8-hour period). According to EPA, there is a statistically significant difference which although small, represents tens of thousands of people at risk.

What kind of health effects would there be less of at the more stringent 0.07 ppm standard—and why do you believe that they are not significant?

Response. In the closure report to the EPA Administrator, CASAC concluded that: "the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations." CASAC then reviewed EPA's quantitative risk assessments. Although EPA's analysis showed differences among the various standard levels,

CASAC stated that: “the ranges are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates.” As a result CASAC concluded: “there is no ‘bright line’ which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of public health.” They further state: “Consequently, the selection of a specific level and number of allowable exceedences is a policy judgment.” This means that CASAC felt there would not be any demonstrable decrease in the health effect endpoints between the two standards.

Table - Summary of CASAC Panel Members Recommendations
(all units $\mu\text{g}/\text{m}^3$)

	PM _{2.5}	PM _{2.5}	PM ₁₀	PM ₁₀
	24-hr	Annual	24-hr	Annual
EPA Staff Recommendation	18 -65	12.5 - 20	150 ¹³	40 - 50
Discipline of Panel Member				
Epidemiologist ¹	20 - 50	no	no	40 - 50
Epidemiologist	20 - 30	15 - 20	no	50
Health Effects Expert	20 - 50 ³	15 - 20	no	40 - 50
Atmospheric Scientist	20 - 50 ³	20 - 30	no	40 - 50 ⁹
Biologist	yes ²	yes ²	150	50
Chest Physician	yes ²	yes ²	150	50
Atmospheric Scientist	yes ^{2,3,12}	yes ^{2,3}	150 ^{3,13}	50
Atmospheric Scientist	yes ^{2,9}	yes ^{2,9}	yes ⁹	yes ⁹
Atmospheric Scientist	yes ^{3,10}	yes ¹⁰	no ^{3,4}	yes ⁴
Epidemiologist ¹	yes ^{2,11}	no	150	yes ²
Atmospheric Scientist	yes ^{3,5}	no	150 ¹³	50
Atmospheric Scientist	yes ^{2,3,6,12}	yes ^{2,3,6}	no	yes ⁹
Toxicologist	50	20	150	50
Atmospheric Scientist	no	20	150	50
Statistics Expert	no	25-30 ⁷	no	yes ²
Chest Physician	≥65	no	150	50
Epidemiologist	75 ⁷	25-30 ⁷	150	50
Biologist	≥ 75	no	150	40 - 50
Atmospheric Scientist ¹	≥75 ^{3,7}	no	150 ³	50
Toxicologist	no ⁸	no ⁸	150	50
Toxicologist	no	no	150	50

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM_{10-2.5} standard rather than a PM₁₀ standard

⁵ concerned upper range is too low based on national PM_{2.5}/PM₁₀ ratio

⁶ leans towards high end of EPA's proposed range

⁷ desires equivalent stringency as present PM₁₀ standards

⁸ if EPA decides a PM_{2.5} NAAQS is required, the 24-hr. and annual standards should be 75 and

25 $\mu\text{g}/\text{m}^3$, respectively with a robust form

⁹ yes, but decision not based on epidemiological studies

¹⁰ low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have PM_{2.5} pollution problems

¹¹ only if EPA has confidence that reducing PM_{2.5} will indeed reduce the components of particles responsible for their adverse effects

¹² concerned lower end of range is too close to background

¹³ the annual standard may be sufficient; 24-hour level recommended if 24-hour NAAQS is retained

¹⁴ George Wolff's recommendation

RESPONSES OF DR. WOLFF TO ADDITIONAL QUESTIONS FROM SENATOR LIEBERMAN

Question 1. The CASAC closure letter on the primary standard portion of the Staff Paper for ozone states, "Although it was the consensus of the Panel that the range of concentrations and allowable exceedances proposed by the Agency were appropriate, a number of Panel members expressed "personal" preferences for the level and number of allowable exceedances. The Staff Paper proposed a range of 8-hour standard concentrations from 0.07 to 0.09 ppm. The Agency proposed to set the standard at 0.08 ppm. Isn't it correct that CASAC reached consensus that the range proposed by the EPA Staff for the ozone standard was appropriate and that the Administrator selected a level from within that range?"

Response. The answer is not that simple. One must consider our closure report as a whole. In the closure report to the EPA Administrator, CASAC concluded that: "the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations." CASAC then reviewed EPA's quantitative risk assessments. Although EPA's analysis showed differences among the various standard levels, CASAC stated that: "the ranges are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates." As a result CASAC concluded: "there is no "bright line" which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health." They further state: "Consequently, the selection of a specific level and number of allowable exceedances is a policy judgment." This means that the decisions to select a given level or number of allowable exceedances within their proposed ranges cannot be based on science.

Question 2. In addition to changing the level of the ozone standard, EPA changed the form of the standard to make compliance easier. Do you agree with EPA's changes in the form of the standard? When CASAC's members made their recommendations as to the level of the standard, did they take into account these changes in the form of the standard?"

Response. First of all the form was not changed to make compliance easier. CASAC recommended that the standard be changed to a more robust (stable) form so extreme and unusual meteorological events do not cause an area, which is close to meeting or has just attained the standard, to bounce in and out of attainment year after year. By making the standard more robust, it is easier to stay in attainment, but it is also more difficult to reach attainment. Even EPA's proposal is still not as robust as some of the members would have liked.

**PREPARED REMARKS
PUBLIC HEARING - U.S. SENATE COMM. ON ENVIRONMENT AND PUBLIC WORKS
FEBRUARY 5, 1997**

ISSUE: Proposed Clean Air Act (CAA) Standards for Ozone (O₃) and Particulate Matter (PM): Are they necessary to protect public health?

SPEAKER: Morton Lippmann, Ph.D., Professor of Environmental Medicine

AFFILIATION: New York University Medical Center

RELEVANT PERSONAL BACKGROUND

1. Academic Peer-Reviewed Research Incorporated into O₃ and PM Criteria Documents, on:
 - a) Respiratory tract deposition and clearance of airborne particles
 - b) Controlled human and animal inhalation studies of physiological responses to acidic particles
 - c) Field studies of population responses to air pollution exposures
 - d) Development and evaluation of air sampling and monitoring techniques
2. Federal Agency Service on Committees Focussing on Inhalation Hazards
 - a) Chair, Clean Air Scientific Advisory Committee (CASAC) (1983-'87)
 - b) Member, CASAC Subcommittees on O₃ (1988-1997) and PM (1993-1997)
 - c) Chair, Physical Effects Review Subcommittee of Clean Air Act Advisory Council (1994-1997)
 - d) Chair, EPA Science Advisory Board (SAB) Review Committee for Risk Assessment for Environmental Tobacco Smoke (1991-1993)
 - e) Chair, SAB Review Committee for Risk Assessment for Dioxin and Related Compounds (1994-1997)
 - f) Co-Chair, 4th Task Force for Research Planning in Environmental Health Sciences, National Institute of Environmental Health Sciences (1992)
 - g) Chair, Board of Scientific Counselors, National Institute for Occupational Safety and Health (1990-1992)
3. Academic Air Pollution Research Study Advisement
 - a) Member and Chair of External Advisory Comm., Harvard 6-Cities Study (1978-1987)
 - b) Member of External Advisory Comm., Harvard - Health Canada - Mult-city Air Pollution Health Effects Study (1987-1991)
 - c) Chair of External Advisory Comm., USC - CA Air Resources Board Study of Effects of Air Pollution on Children (1992-present)

OUTLINE OF STATUTORY AND SCIENTIFIC BASIS FOR PROPOSED O₃ AND PM STANDARDS

1. Statutory Requirement Mandates Periodic (Nominally 5 yr) Reviews of Adequacy of National Ambient Air Quality Standards (NAAQS)
2. There is growing Scientific Peer-Reviewed Evidence for Adverse Human Health Effects at Ambient Concentrations within Previous NAAQS for PM (revised in 1987) and O₃ (last revised in 1979)
3. There have been extraordinarily Thorough Reviews of Evidence were Conducted by EPA, CASAC, and Public Sector. They provide an Open Record for EPA Administrator and Congress
4. There were Strong CASAC Consensus Conclusions with Respect to:
 - a) Need for more targeted indices of relevant exposure, e.g., 8-hr avg. O₃, and 2.5 µm cut-size for PM (PM_{2.5})
 - b) Need for more robust criteria for daily NAAQS exceedances, i.e., multiple times rather than single
 - c) Adverse health effects are occurring in U.S. communities currently in compliance with existing NAAQS
 - d) Adverse effects are evident for sensitive subpopulations and may not affect most people (very large numbers of affected people, but low % of total population)
 - e) There are no identifiable threshold exposures for associations between PM and O₃ concentrations and adverse health effects
 - f) PM_{2.5} and O₃ are largely formed in the atmosphere from gaseous precursors, are relatively uniformly distributed over large regions (hydrocarbons and nitrogen oxides (NO_x) react to form O₃, and organic components of PM_{2.5}; NO_x, SO₂ and photochemical oxidants react to form inorganic components of PM_{2.5} (sulfates and nitrates)
 - g) Control strategies for PM_{2.5} and O₃ need to be implemented together and on broad geographic scales
 - h) Existing statutes and evidence thus presents difficult policy dilemmas to EPA Administrator and Congress (reducing PM and O₃ concentrations can reduce, but not eliminate, excess mortality and morbidity)

5. Further Conclusions on PM by CASAC Panel Members with Relevant Experience in Environmental Epidemiology (excerpts from supplemental letter of 3/30/96 by Lippmann, Shy, Speizer, and Stolwijk-Appendix H of PM Staff Paper).

In our judgment, the studies reviewed in the criteria document, specifically those considered in Chapter 12 (Epidemiological Studies), are persuasive in demonstrating a causal relationship between particulate air pollution, as measured by different methods in the various studies, and excess mortality and morbidity.

The reasons for concluding that particulate air pollution is causally related to excess mortality and morbidity are summarized here:

- A large number (20) of epidemiological time-series studies have consistently found a statistically significant association between daily variation in particulates and total mortality in cities of the U.S., Canada, Latin America, the U.K., and continental Europe. These findings argue against the associations being attributable to statistical sampling variation, i.e., the role of chance.
- The results of these time-series studies cannot be attributed to the vagaries of statistical modeling, nor to confounding by season or weather.
- The results of the time-series studies cannot be attributed to other criteria air pollutants.... Across the range of the 20 studies mentioned above, particulate air pollution is the only pollutant that is consistently associated with excess daily mortality, and the estimate of its effect is relatively stable when adjusted for the presence of co-pollutants. No monitored air pollutant, other than particulate matter, can account for the consistently observed excess mortality in these studies. Excess morbidity from cardiopulmonary diseases has also been observed in a considerable number of studies, and the morbidity relationship with ambient particulate concentrations is stronger overall and more consistent than for any other air pollutant.
- There is considerable coherence between the observed mortality and morbidity effects of particulate air pollution. Not only is excess mortality from cardiovascular and respiratory diseases observed, but on days of higher particulates excess hospitalizations for cardiovascular and respiratory diseases are reported. On days of high particulates, there is an increased proportion of deaths from chronic obstructive pulmonary disease, pneumonia, heart disease and deaths among the elderly than on days of low particulates. These findings are supportive of a causal role for particulate air pollution, since they are health endpoints one would most anticipate from exposure by the inhalation route.

Given the striking consistency of the above studies, their robustness to variations in statistical modeling, the coherence among different but closely related health endpoints, and the empirical elimination of any alternative explanation for the findings, we conclude that a causal interpretation for particulate air pollution exposure is reasonable and defensible. This conclusion is further supported by longitudinal cohort studies of populations in which a geographical gradient in particulate air pollution was associated with a corresponding gradient in total mortality, in cardiopulmonary mortality and in lung cancer. These studies carefully controlled for other individual risk factors for these health endpoints.

Although population exposure to air pollution cannot be perfectly estimated based on central monitoring, these inherent errors in exposure estimation are more likely to cause an underestimation of the adverse health effects associated with pollution exposure, particularly in longitudinal cohort studies where individual risk factors and exposures are directly related to health effects. Thus the consistent positive findings cannot be attributed to exposure measurement error. Furthermore, there is growing evidence that fine particles are more uniformly distributed over large geographic areas than are coarse particles, that measurements at one site give a reasonable estimate of the fine particulate concentrations across a city, and that fine particles penetrate and have longer lifetimes indoors than coarse particles. This evidence supports using ambient measures of fine particulates at a central site as an acceptable estimate of the average exposure of people in the community. For these reasons, we judge that uncertainties arising from air monitoring and human exposure estimation do not negate the consistent excess mortality and morbidity associations discussed above.

We believe that the case has been made that fine particulates, as measured by $PM_{2.5}$, are the best surrogate currently available for the component of particulate air pollution that is associated with excess mortality and morbidity. We are not claiming that $PM_{2.5}$ is the causal agent, but rather that $PM_{2.5}$ is a better measure than any alternative metric, of the complex in the particulate mass that is causing excess mortality and morbidity. Excess mortality, hospital admissions for respiratory diseases and decreased lung function are more strongly and consistently associated with fine rather than with coarse mode particulates.

The Health Effects Institute (HEI) reanalysis does not contradict any of the above conclusions. The HEI analysis conclusively demonstrated that the positive findings from the original studies selected for reanalysis were replicable, were not an artifact of statistical modeling, and were not confounded by idiosyncrasies in the method to control for season or weather. The HEI investigators appropriately concluded that, because of the high intercorrelations between pollutants in Philadelphia, mortality effects could not be attributed solely to particulates. More importantly, in their further report on this phase of their study, they concluded that "insights into the effects of individual criteria pollutants can be best gained by assessing effects across locations having different pollutant mixes and not from regression modeling of data from single locations."

In our judgment, EPA has appropriately synthesized this evidence and drawn a responsible public health conclusion, namely, that particulate concentrations at current levels are causally associated with excess mortality and morbidity. Furthermore, we agree that fine particulates, as currently indexed by $PM_{2.5}$, are the most appropriate indicator for the component of the particulate air mass to which these adverse effects are attributed. We also agree that some adverse health effects may be related to the coarse particulate mode, and that therefore it is desirable to consider fine and coarse mode particulates as separate candidates for air quality standards.

MY RECOMMENDATIONS TO CONGRESS

1. Recognize that EPA Administrator has made a prudent public health judgment in her PM and O₃ NAAQS selections.

The health benefits (cost avoidance) to be derived by implementation of the new PM_{2.5} NAAQS will far exceed the costs of control implementations. The benefit/cost ratio for implementing compliance with the revised O₃ NAAQS is not as great, but it should be recognized that reductions in O₃ formation will also reduce PM_{2.5} formation and ambient air concentrations and will also therefore contribute to the benefits associated with reductions in PM_{2.5} exposures.

For O₃, the current NAAQS of a 1-hr max of 120 ppb not be exceeded more than 4 times in 3 yrs is equivalent to an 8-hr max of 90 ppb based on the 3rd highest 8-hr value in a year. Thus, the proposed 8-hr max of 80 ppb is only a modest O₃ NAAQS reduction. By contrast, the Air Quality Guideline for O₃ of the World Health Organization-European Region (WHO-EURO), adopted late in 1996 is an 8-hr maximum of 60 ppb. In my view, the 8 hr-80 ppb proposal is a prudent step in the right direction at this time and recognizes that any lower limit is probably not achievable without draconian controls. The major advance is the shift to an 8-hr averaging time, providing a much sounder basis for evaluating the public health risk from community exposures.

For PM₁₀, the 50 µg/m³ annual average would be retained without change, and the 24-hr PM₁₀ would be relaxed by applying it only to the 98th% value (22nd highest) rather than to the 4th highest over 3 yrs. It is only by implementing the new PM_{2.5} NAAQS that the degree of public health protection would be substantially advanced, and then only in the eastern U.S. and in some large cities in the west where fine particles are major %s of PM₁₀.

2. Recognize that 1990 CAA-Title I implementation already underway (SO₂ and NO_x emission reductions) will reduce the numbers of communities in exceedance of the proposed PM_{2.5} NAAQS relatively soon.
3. Recognize that the new PM_{2.5} NAAQS cannot be implemented immediately, and prudent implementation schedules can be devised and implemented to minimize economic disruptions.
4. Recognize that the causal factors within PM_{2.5} for the consistent and coherent associations between PM_{2.5} in community air and excess daily and annual mortality, excess emergency room and hospital admissions for respiratory diseases, lost time from work and school, respiratory symptoms, and reduced lung functions are not yet established in terms of biological mechanisms. However, it has clearly been shown that they cannot be attributed to other hypothesized environmental factors such as other criteria air pollutants, aeroallergens, or meteorological variables. The situation is analogous to that for another commonly encountered respiratory irritant, i.e., environmental tobacco smoke, where the epidemiological evidence for adverse respiratory effects in children is overwhelming, and there is significant evidence for excess lung cancer in adults as well.
5. Recognize that more definitive laboratory and epidemiological research on causal factors is now becoming feasible as epidemiologic investigative techniques and animal models for susceptible segments of the population are being established and validated. With a reasonable and prudent level of additional research funding for EPA and NIEHS, identification of the biological mechanisms, the chemical and physical properties of the active components of PM, and the exposure-response relationships, can be more firmly established within the next five years. Such knowledge is essential for the design and implementation of cost-effective control strategies, and for the further revisions of the PM NAAQS that will be required early in the next century.

6. **Recognize that while the costs of the research recommended above are substantial (on the order of $\$50 \times 10^6$ per year), they are quite small in relation to the control costs that can be more effectively targeted and reduced through the knowledge gained, and also small in comparison to the health benefits resulting from exposure reductions resulting from the controls.**

RESPONSES OF DR. LIPPMANN TO ADDITIONAL QUESTIONS FROM SENATOR HUTCHISON

Question 1. Dr. Lippmann in your statement, you take a very strong position that EPA has appropriately synthesized the available evidence and drawn a responsible health conclusion that particulate concentrations at current levels are causally associated with excess mortality and morbidity. You go on to state that you are not claiming that the $PM_{2.5}$ level is the *causal agent* but that it is the *best measure* of any other metric level. As we have determined, there was no unanimous agreement on the particulate standard. Considering EPA's proposal completely, as I understand, the only unanimous agreement was in ozone, which was to replace the 1 hour exposure standard with an 8-hour standard.

Response. With regard to the proposed $PM_{2.5}$ standard, 19 of 21 Panel members agreed that one was needed. The basis was that there was a closer association between $PM_{2.5}$ and excess mortality and morbidity than with any other previously used measures of fine particle concentration. We do not yet have sufficient monitoring data on the concentrations of $PM_{2.5}$ components to determine whether any of them would produce even better degrees of association. If future research can establish better associations of this kind, then the fine particle standards to be established in the next century can be based on them.

Question 2. If these standards are accepted, can you say definitively how quickly the effectiveness can be measured (such as a reduction in childhood asthma and mortality rates, due to respiratory diseases)?

Response. With regard to the timeframe for being able to observe reductions in adverse health effects due to ozone and fine particles, no clear answer is possible at this time. One factor is the timetable for implementation of the revised standards. Benefits can only begin to occur after airborne concentrations actually come down. For those effects which result from periodic peak exposures, such as exacerbation of asthma, the frequency should go down in proportion to the reductions in exposure. On the other hand, for excess annual mortality and baseline reductions in lung capacity, which are attributable to long-term chronic exposures and the damage they produce, there is likely to be a lag of several years, or even decades, before the rates improve.

 RESPONSES OF DR. LIPPMANN TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. You stated that it makes sense to set standards for ozone and $PM_{2.5}$ at the same time. Could you explain why this is and what the advantages are of regulating ozone and $PM_{2.5}$ together?

Response. With regard to the advantages of setting standards for ozone and $PM_{2.5}$ at the same time, the main reason is that both pollutants are secondary pollutants that form in the atmosphere following chemical reactions among gaseous precursors. The gaseous precursors come from broadly distributed common sources, especially stationary source combusters and motor vehicles, and a common control strategy will be needed to reduce them. The photochemical reaction sequences that require hydrocarbon vapors, nitrogen dioxide, and sunlight lead to ozone formation also lead to the formation of organic fine particles and hydroxyl ions. The hydroxyl ions accelerate the transformation of sulfur dioxide and nitrogen oxide vapors from combusters into nitric and sulfuric acids and their neutralization products, which are also fine particles.

Question 2. An issue was made over the relative risk factor for the $PM_{2.5}$ studies—whether it was too low to support a sufficient degree of scientific certainty. Can you explain the use of the relative risk factor and how it applies to the $PM_{2.5}$ debate?

Response. With regard to the relative risk (RR) factors obtained from the epidemiological studies based on $PM_{2.5}$ and PM_{10} , the relatively low RR values indicate that only a small fraction of the overall population has been affected. However, a very small fraction of a very large population can account for large numbers of affected people and a relatively large population impact in relation to other hazards associated with exposure via air, drinking water, foods, etc. Many of the macroepidemiological studies reporting RR values at about 1.05 were based on large city populations. Most of them indicate statistically significant exposure-response relationships and none of the suggested confounding factors has accounted for the generally consistent findings.

RESPONSES OF DR. LIPPMANN TO ADDITIONAL QUESTIONS FROM SENATOR LIEBERMAN

Question 1. One of the criticisms of the science of particulate matter is that when you look at results from particular cities and add different corrections for heat and humidity, or break up the analysis of a year's worth of data to look at a specific season or day, the data appear to contradict the results from earlier studies. What are the dangers of looking at only small portions of an entire data set? Is it reasonable that a small subset of the data might be contradictory while the weight of evidence suggests that there are severe consequences of particulate matter pollution? Has any reevaluation of epidemiological studies on particulate matter been performed that contradicts the earlier results?

Response. With regard to the interpretation of diverse epidemiological studies in different cities, it is relatively easy to find apparent disagreements among the analysts. Some of it derives from the limited statistical power of some studies to detect an association that is real because of the quality or size of the available data bases. Other disagreements arise because of the different modelling choices made by the analyst. What is truly remarkable about the epidemiological studies with PM is their overwhelming consistency in finding small but significant excess risks in studies having the statistical power to detect such risks. Some of the analysts who want to negate such risks often segregate their data into smaller subsets which limits their analytic power, or they use less appropriate models or assumptions than the mainstream group of experienced analysts.

Question 2. Isn't it correct that CASAC heard testimony from a wide range of scientists, including Dr. Smith and Dr. Wyzga, and still decided that the science was sufficient for EPA to make a regulatory decision on setting a standard for fine particles?

Response. Drs. Smith and Wyzga had ample opportunity to present their analyses and findings to CASAC during the various public review sessions. They also had the opportunity to interact with the Panel and respond to the Panel members questions following their presentations. The CASAC consensus followed these discussions.

Question 3. Did the CASAC panel on which you served in 1989 conclude that the current ozone standard provides "little, if any" margin of safety?

Response. The CASAC panel did, in fact, conclude in 1989, that the 1-hr, 120 ppb, 1-exceedance standard for ozone provides "little, if any" margin of safety.

Question 4. In addition to proposing a level of the PM_{2.5} standard, EPA proposed a form of the standard to make compliance easier. When CASAC's members made their recommendations, did they take into account these changes in the form of the standard? Is it possible to compare directly the personal preferences of CASAC members and the level of the standards EPA ultimately proposed?

Response. When the CASAC members were asked by Dr. Wolff to express their personal preferences for a 24 hr PM_{2.5} standard, they had already reached a consensus judgment that a multiple exceedance form was desirable. However, they did not, nor could they, know that the Administrator would select a 98th percent form, i.e., permitting 7 daily exceedances in an average year. I believe most members were thinking of 3 to 5 permissible exceedances. In any case, there is no great difference among these numbers of exceedances in stringency for a given numerical concentration limit.

Question 5. Dr. Wyzga testified that a number of uncertainties make attribution of premature death and illness to particulate matter exposure difficult. Have you evaluated these issues? Could you comment on the nature of these uncertainties? In your view, do they prevent attributing premature death and illness to particulate matter pollution?

Response. It is difficult to make a precise attribution of premature death and illness to PM because of our limited abilities to precisely characterize relevant PM exposures and to make appropriately allowances for other causes of mortality and morbidity in large populations. Thus, there is uncertainty about the extent of the response attributable to PM. On the other hand, the overwhelming consistency and coherence of the responses seen in numerous studies in cities having different climates and pollution mixtures leaves little doubt that PM is causing at least some substantial number of cases of excess mortality and morbidity at concentrations below the current standard.

Question 6. Dr. Wyzga also testified that no one knows if the proposed particulate standards will lead to improvements in public health. What is your view of that conclusion?

Response. It follows clearly that since current PM exposures are causing excess mortality and morbidity, and exhibit no evidence for a threshold for such effects,

that the proposed standards, which provide for some reductions in permissible exposure will lead to proportionate improvements in public health.

RESPONSES OF DR. LIPPMANN TO ADDITIONAL QUESTIONS FROM SENATOR BOXER

Question 1. Scientific studies show that healthy adults can suffer a temporary loss of lung function of 20 to 60 percent if they exercise outside during summer months. In the face of this evidence, industry representatives claim that this is not a health effect because it is a temporary and reversible effect. What in your personal view, is a health effect?

Response. Temporary losses of lung function are a measurable effect in natural populations engaged in outdoor recreation at ozone concentrations as low as 0.06 ppm. In controlled ozone exposure studies at 0.08 ppm lasting 6.6 hours with moderate exercise, some healthy adults have function decrements that are greater than 20 percent and by common consent, and by CASAC endorsement, such decrements are considered adverse responses. Importantly, such chamber exposures also produce evidence of lung inflammation and enhanced responsiveness to bronchial airway stimulants. While the respiratory function responses are no longer detectable the next day, the other, potentially more serious responses do not disappear as rapidly. In asthmatic children exposed to ozone at a summer camp where concentrations were within the current standard, there were more symptoms and extra medication usage in proportion to the ozone concentration in the air, as well as reduced lung function. Such responses in these children with compromised health status is clearly an adverse effect.

We also know that ozone, at low concentrations results in excess emergency room and hospital admissions for respiratory diseases conditions. Furthermore several recent papers, not available at the time of CASAC closure, document excess mortality associated with peak ozone exposures that is independent of PM effects on daily mortality.

Question 2. Why does the bottom of the recommended range stop at 0.07 parts per million of ozone? What are the health effects that influence your judgment?

Response. The designation of 0.07 ppm as the lower bound of the range was based on the EPA Staff judgment that the effects remaining at that level were too small and/or affected too few people to warrant considering them adverse from a public health perspective.

Question 3. On March 20 1996, you and three other members of the CASAC panel on Particulate Matter sent a letter to EPA Administrator Browner giving additional views on PM. Would you please briefly summarize that letter?

Why did you write the letter? Do you believe that the four of you that signed that letter had any special expertise that other members of the CASAC panel; did not share?

Response. The letter that you refer to is available in full as Appendix K of the EPA Staff Paper for Ozone. It is available to you in abbreviated form in my formal prepared remarks, which I submitted prior to the February 5 Hearing.

We wrote the letter because of our concerns that the CASAC letter, which we endorsed as a summary consensus statement on key issues, did not provide all of the critical health effect issues and concerns in sufficient detail to guide the EPA Staff in the preparation of their final version of the Staff Paper. We felt that we, collectively, had more relevant direct experience on the interpretation of the air pollution epidemiology than most other members who were selected for expertise in areas such as ecological effects, meteorology, sampling and analyses, clinical medicine, etc.

Question 4. Some industry experts say we should wait before we set a new PM_{2.5} standard until we conduct research to identify the exact causal agent. In other words, determine exactly what component is causing the premature deaths and illness. Why should we not wait?

Response. If we wait, we will deny protection against the known adverse effects that current exposures within the existing PM₁₀ standards are producing. Also, we would not be moving against sources of fine particle precursor gases as effectively as we could if we have PM_{2.5} standards.

Question 5. Industry asserts that human chamber studies of ozone are not representative of real exposures because artificially produced ozone is used and activities do not represent real world activities. Are these assertions correct?

Response. To the extent that the chamber studies are unrealistic, it is because they tend to underestimate the effects produced by ozone in natural settings, and because they are largely conducted using populations that do not include representatives of the most sensitive subpopulations. In my own research on children and

adults in natural settings, I have seen greater responses to ozone than those reported in the controlled exposures in chambers. Healthy children have greater functional responses than children in chambers. Many of the healthy adults engaged in lunchtime jogging or brisk walks in a rural setting self-selected exercise levels greater than those considered very high by chamber investigators and had functional decrements after half-hour exposures comparable to 2-hour exposures in chambers. In our studies of asthmatic camp children, we found comparable functional responses to healthy children but for lower breathing rates, and we also found asthma exacerbations in terms of more frequent symptoms and increased medication usage.

Question 6. Industry discounts studies showing health effects of ozone on children in summer camp because they are exposed not only to ozone, but to other pollutants and allergens which may cause which may cause the adverse affects.

Response. In the summer camp studies the children are also exposed to other pollutants and allergens. However, their functional responses to ozone are not measurably influenced by these other exposures and they go up and down with ozone concentrations. Thus, it is only by controlling ambient ozone levels that the effects can be reduced.

PREPARED STATEMENT OF DR. GEORGE D. THURSTON, SC.D., ASSOCIATE PROFESSOR, DEPARTMENT OF ENVIRONMENTAL MEDICINE, NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Mister Chairman and members of the Subcommittee, I am George D. Thurston, a tenured Associate Professor of Environmental Medicine at the New York University (NYU) School of Medicine. My scientific research involves investigations of the human health effects of air pollution.

I am also the Director of the National Institute of Environmental Health Sciences' (NIEHS) Community Outreach and Education Program at NYU. A goal of this program is to provide an impartial scientific resource on environmental health issues to decisionmakers, and that is my purpose in speaking to you here today.

Ozone (O₃) is a highly irritant gas which is formed in our atmosphere in the presence of sunlight from other air pollutants, including nitrogen oxides and hydrocarbons. These "precursor" pollutants, which cause the formation of ozone, are emitted by pollution sources including automobiles, electric power plants, and industry.

The adverse health consequences of breathing ozone at levels below the current U.S. National Ambient Air Quality Standard (NAAQS) of 120 parts per billion (ppb) are serious and well documented. This documentation includes impacts demonstrated in controlled chamber exposures of humans and animals, and observational epidemiology showing consistent associations between ozone and adverse impacts across a wide range of human health outcomes. The noxious nature of ozone is also evidenced by the way it visibly "eats away" at materials such as rubber, an elastic substance sharing characteristics with human lungs.

Observational epidemiology studies have shown compelling and consistent evidence of adverse effects by ozone below the current U.S. standard. These studies follow people as they undergo varying real-life exposures to pollution over time, or from one place to another, and then statistically intercompare the health impacts that occur in these populations when higher (versus lower) exposures to pollution are experienced. These epidemiologic studies are of two types: (1) population-based studies, in which an entire city's population might be considered in the analysis; and (2) cohort studies, in which selected individuals, such as a group of asthmatics, are considered. Both of these types of epidemiologic studies have shown confirmatory associations between ozone air pollution exposures and increasing numbers of adverse impacts, including:

- decreased lung function (a measure of our ability to breathe freely);
- more frequent asthma symptoms;
- increased numbers of asthma attacks;
- more frequent emergency department visits;
- additional hospital admissions, and;
- increased numbers of daily deaths.

In my own research, I have found that ozone air pollution is associated with increased numbers of respiratory hospital admissions in New York City, Buffalo, NY, and Toronto, Ontario, even at levels below the current standard of 120 ppb. My ozone-hospital admissions results have been confirmed by other researchers considering locales elsewhere in the world. The U.S. EPA used my New York City asthma results in their "Staff Paper" when estimating the health benefits of lowering the ozone standard. However, they failed to consider other respiratory admissions af-

ected, such as for pneumonia or bronchitis. Thus, considering the published results from various cities, the EPA analysis underpredicts the respiratory hospital admission benefits of their proposed regulations by about a factor of two.

This month, the results of a study I conducted on the effects of air pollution on children at a summer "asthma" camp in Connecticut will be published. This study of a group of about 50 moderate to severely asthmatic children shows that these children experience diminished lung function, increased asthma symptoms, and increased use of unscheduled asthma medications as ozone pollution levels rise. On the highest ozone days, the risk of a child having an asthma attack was found to be approximately 40 percent greater than on an average study day, with these adverse effects extending to below 120 ppb O₃.

More recently, I have found that daily mortality also rises after high ozone days in the U.S. cities of New York City, Atlanta, Detroit, Chicago, St. Louis, Minneapolis, San Francisco, Los Angeles, and Houston, even after accounting for other factors such as season and weather, and at ozone levels below the current NAAQS. I find that the risk of death rises by about 6 percent on ozone days having a 1-hour maximum of ozone that is 100 ppb above the average. While not yet published, these U.S. results are supported by previously published results, and by a recent spate of new papers by other researchers showing similar associations between ozone and human mortality around the globe. Recently published studies have shown this relationship in: London, Amsterdam, and Belgium. In addition, papers recently submitted for publication have also shown similar associations between ozone exposure and human mortality in both Rotterdam, the Netherlands, and Brisbane, Australia.

It is important to keep in mind that the above described epidemiology is supported by a large body of knowledge from controlled exposure studies that give consistent and/or supportive results, and that have demonstrated pathways by which ozone can damage the human body when it is breathed. Clinical studies have demonstrated decreases in lung function, increased frequencies of respiratory symptoms, heightened airway hyper-responsiveness, and cellular and biochemical evidence of lung inflammation in healthy exercising adults exposed to ozone concentrations as low as 80 parts per billion for 6.6 hours.

Airway inflammation in the lung is among the serious effects that have been demonstrated by controlled human studies of ozone at levels typically experienced by most Americans. Airway inflammation is especially a problem for children and adults with asthma, as it makes them more susceptible to having asthma attacks. For example, recent controlled human studies have shown that prior exposure to ozone enhances the reactivity of asthmatics to aeroallergens such as pollens, which can trigger asthma attacks.

In addition, increased inflammation in the lungs can make the elderly more susceptible to pneumonia, a major cause of illness and death in this age group.

It has been argued that, since the prevalence of asthma has risen over the last decade while air pollution levels have not, air pollution cannot be affecting asthma. However, this is not correct. This trend merely indicates that air pollution probably does not cause people to become asthmatic, but it does not contradict the fact that air pollution adversely affects those who already have asthma. Indeed, as the asthma "epidemic" causes the number of persons with asthma to rise, whatever the cause of this "epidemic" turns out to be, there is a bigger and bigger percentage of the U.S. public who can be severely affected by air pollution.

The EPA has proposed a standard of 80 ppb averaged over an 8-hour period, rather than the existing 120 ppb limit for the highest hour of each day. The switch to an 8-hour average is clearly appropriate, based on the scientific evidence that the cumulative effects of multiple hours of exposure are worse for people than a single peak hour of exposure. However, since significant adverse effects are well documented down to the 80 ppb level, the EPA proposal provides no margin of safety. This is especially true since the proposed law will allow several exceedances of this level before a violation is cited. Thus, the health evidence would indicate that a standard set at 70 ppb ozone averaged over an 8 hour period is needed, if any margin of safety is to be provided to the public, rather than the 80 ppb recommended by the EPA.

On this subject, it is interesting to note what levels other deliberative bodies have recommended regarding permissible ozone levels. In Canada, the daily 1-hour maximum allowed is 80 ppb of ozone, which is roughly equivalent to an 8 hour limit of about 60 ppb ozone. In addition, The World Health Organization (WHO) recently released their "Update and Revision of the Air Quality Guidelines for Europe", and they similarly recommended an 8-hour average guideline of 60 ppb for ozone. Also, the American Conference of Governmental Industrial Hygienists (ACGIH) has recently proposed lowering the widely employed workplace Threshold Limit Value—Time Weighted Average (TLV-TWA) limit for ozone to 50 ppb over an 8-hour work

day for workers under heavy exertion. This would indicate that healthy American workers need to be protected from levels that would be perfectly legal for the rest of us to breathe under the US EPA's proposals. The EPA's new proposed ozone limit is weak when compared to standards set or recommended by others.

It is also important to remember that the EPA proposed ozone standard is less stringent than the O₃ limit that prevailed in the U.S. during the 1970's, before the EPA decided to relax the limit to 120 ppb in February, 1979. Until that time, our standard was the same as the Canadians: 80 ppb ozone as a daily 1 hour maximum, or equivalent to about a limit of 60 ppb when averaged over 8 hours. Thus, while the EPA proposal is more stringent than the existing law, it is far less restrictive than the law of the land in the U.S. during the 1970's.

In conclusion, I would like to reiterate the key messages contained in the letter that I and 26 other air pollution researchers and physicians sent to President Clinton last month:

- Please listen to the medical and scientific community on this issue.
- Exposures to O₃ and PM air pollution have been linked to medically significant adverse health effects.
- The current NAAQS for these pollutants are not sufficiently protective of public health.

Thank you for the opportunity to speak to you on this important issue.

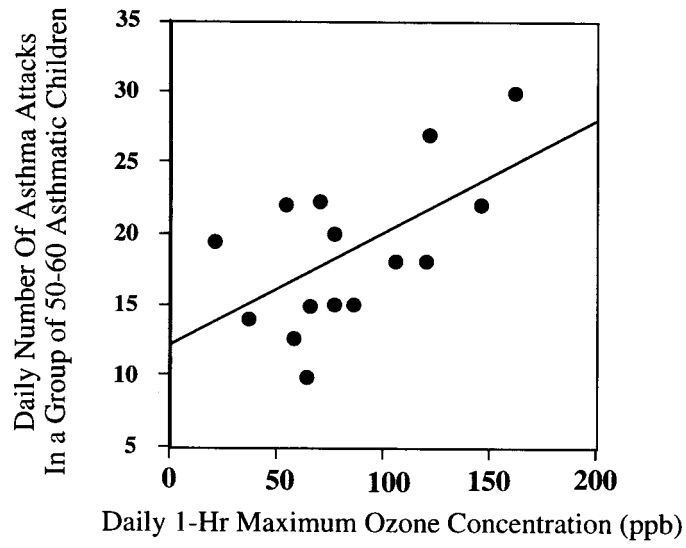
RESPONSES OF DR. THURSTON TO ADDITIONAL QUESTIONS FROM SENATOR LIEBERMAN

Question 1a. Are hospital admissions the only indicator of adverse health effects due to ozone?

Response. Looking only at the asthma hospital admissions effects of ozone gives an extremely narrow insight into the wide scope of adverse consequences presently experienced by the public as a result of ozone exposure. We know, from published research, that hospital admissions resulting from ambient ozone are near the tip of an "iceberg" of adverse health effects from ozone exposure. Beneath this "visible" tip of the iceberg are effects not routinely documented, such as emergency department visits, asthma attacks, emergency visits to private physicians, increased medication use, restricted activity days (e.g., work days lost), more frequent respiratory symptoms, diminished quality of life (e.g., due to reduced ability to walk up stairs, etc.), and other impacts of which we are as yet unaware. For example, as detailed later in this response, available studies indicate that, for every ozone induced asthma hospital admission recorded, there are another 7 persons who became ill enough because of ozone to require a visit to the hospital emergency department (ED), and some 700 asthma attacks because of ozone. Thus, it would be a serious mistake to think that counts of emergency hospital admissions resulting from ozone exposure even begin to reflect the much larger scope of the adverse human health effects and the medical costs presently being visited upon the American people by ozone exposures, especially among children and the elderly.

For example, I recently conducted an epidemiologic study following approximately 55 children with moderate to severe asthma attending a summer "asthma camp" in eastern Connecticut ("Summertime Haze Air Pollution and Children with Asthma", published in the *American Journal of Respiratory and Critical Care Medicine*. 1997. Vol. 155. pp. 654-660). The results of this study showed that increasing numbers of these children experienced debilitating asthma attacks when ozone pollution levels increased, as displayed in the attached figure entitled, "Daily Asthma Attacks in Children Increase as Ozone Levels Rise". However, none of these children ended up at the hospital to be "counted" as hospital admissions. Thus, many asthmatics who suffer attacks just suffer in silence, or visit their private doctor, or visit a hospital emergency department. However, since they were never formally admitted to a hospital, we don't have the statistics to document their suffering, so that these impacts are ignored by risk assessments based solely on hospital admissions.

DAILY ASTHMA ATTACKS IN CHILDREN INCREASE AS OZONE LEVELS RISE



Question 1b. What are the limitations of the U.S. EPA's risk assessment in this regard?

Response. There are several problems associated with the EPA hospital admissions risk assessment discussed at this hearing: one has to do with the inherent limitations in all such risk assessments; one has to do specifically with EPA's narrow focus in this risk assessment case; and one has to do with the way the EPA risk assessment results are being used out of context.

First, risk assessment is ultimately, a reductionist exercise which considers only the health outcomes and effects for which data happen to be available. In epidemiology, which provides a key input to risk assessment, we are largely limited to "looking under the lamppost" for effects. This is because the expense of collecting the data required to assess all of the potential effects are beyond the allocated research budgets of most or all funding sources. As a result, we often look at available routinely collected records, such as for mortality and hospital admissions. But even these data are limited. Most States have only recently started uniform collections of hospital admissions records, and many still do not. With mortality, the cause of death is poorly reported, and death counts are available by county, limiting our ability to conduct mortality studies focused on key population subsets or locations. More importantly, most of the health outcomes which should be considered by risk assessments are not, merely because data records for them just don't exist. Thus, the risk assessment process is fated to consistently underrepresent the scope of the health impacts resulting from environmental contaminants.

In this specific risk assessment case, the EPA OAQPS Ozone Staff Paper (EPA-452/R-96-007) asthma hospital admissions risk assessment biases the scope of the ozone effects estimates downward further, because it presents only a subset of the adverse outcomes that we have documented as resulting from ozone exposure, and because the most relevant denominator has not been used in calculating percentages. Indeed, as I noted in my written and oral testimony, even for respiratory hospital admissions the numbers used by the EPA underestimate the expected ozone cleanup benefits by approximately a factor of two, as non-asthma respiratory admissions are ignored. Furthermore, there are, as noted above, many additional adverse outcomes experienced by the public as a result of ozone exposure that are not reflected by hospital admissions.

Lastly, the EPA hospital admissions risk assessment numbers are now being used "out of context", which can be misleading. In the Staff Paper, it is clearly stated that the EPA risk assessment "does not cover all health effects caused by O₃" and that "the risk assessment is intended as a tool that may, together with other information in this Staff Paper and in the CD, aid the Administrator in judging which alternative O₃ NAAQS provides an adequate margin of safety." Thus, the original EPA risk assessment was not aimed at providing a complete picture of the reductions in effects of ozone to be achieved, and should not be interpreted in this way.

Question 1c. Senator Chafee showed you a chart at the hearing concerning reductions in hospital admissions due to asthma from a changed ozone standard. Can you comment on this chart?

Response. The chart regarding hospital admissions in New York City shown at this hearing was based upon Table VI-2 (revised) entitled "Estimated Hospital Admissions for Asthmatics in the New York City Area" from the November 30, 1995 letter "CASAC Closure on the Air Quality Criteria for Ozone and Related Photochemical Oxidants" from Dr. George T. Wolff of General Motors to Carol M. Browner of the U.S. EPA, which was itself derived from Table VI.2 of the EPA OAQPS Ozone Staff Paper (pg. 158). This chart has several major weaknesses as an input to decisionmaking: (i) it embodies only a small fraction of the numerous health benefits which can be achieved by lowering ambient ozone levels; (ii) comparisons of the ozone-related asthma hospital admissions with total annual asthma admissions are not the most appropriate way to evaluate these estimated ozone health impacts, and; (iii) the validity of the EPA ozone proposal, which was based upon an exhaustive and comprehensive review of all of the available information regarding ozone health effects, should not be evaluated solely upon an appraisal of a single study or health outcome, which seems to be happening here.

These chart weaknesses are elaborated upon in more detail below.

(i) The chart presented at the hearing considers only a single health outcome, asthma hospital admissions in New York City, when we know that ozone induced health effects are being experienced elsewhere in the U.S., and that there are a myriad of other significant adverse health effects of air pollution that are occurring in the public, but are not reflected in this table.

The adverse health effects ignored in the chart include both the hospital admissions that occur for causes other than asthma, and the effects felt by people who

are adversely affected, but who never get admitted to the hospital, such as those requiring emergency room visits or private physician visits, and children experiencing asthma attacks. When these other significant adverse effects of ozone are considered, the number of people adversely affected rises by many orders of magnitude over the numbers indicated in this table.

Moreover, this table considers only one city (one of the few for which suitable asthma admissions data have been routinely collected) representing only 8 million of the approximately 122 million people in the United States living in areas not now in compliance with the proposed ozone standard.

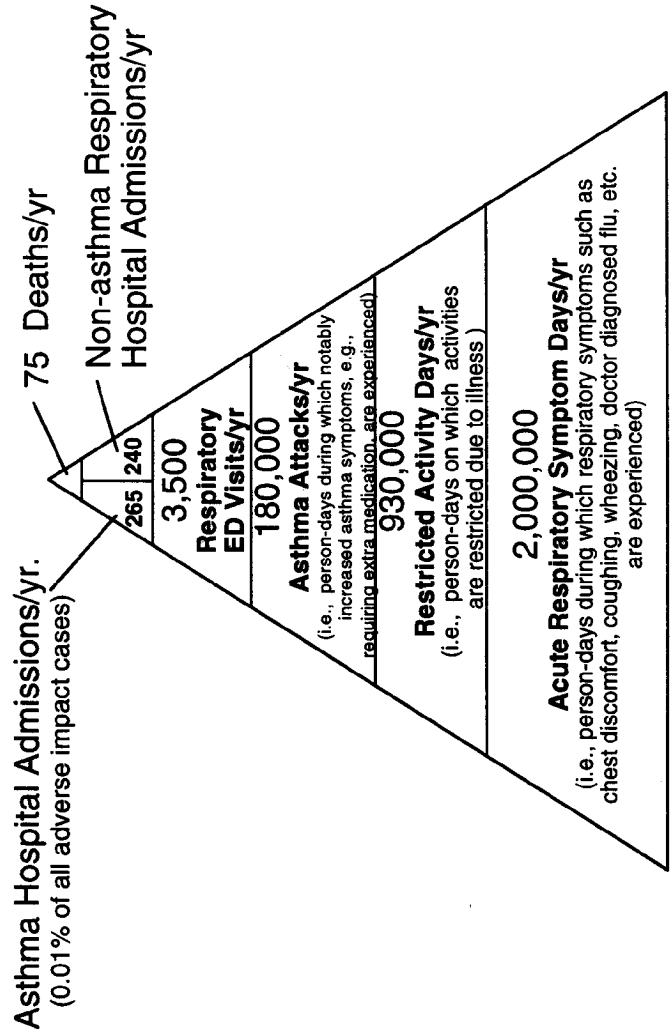
Thus, the numbers in the hearing chart should not be viewed as in any way presenting the full extent of adverse human effects from ozone air pollution. Indeed, even for the outcome considered, hospital admissions, it is an underrepresentation. Looking over the various cities that I have considered, the estimated ozone effects on other respiratory categories such as pneumonia and bronchitis are of about equal size as those shown for asthma, and this does not consider other disease categories which have been shown to be adversely affected by air pollution in the past (e.g., cardiac admissions). Thus, for hospital admissions these numbers are an underestimate of at least a factor of two.

The numbers in the chart presented at the hearing are most appropriately viewed as one important signal that significant adverse effects are occurring in the general public. It is critical that it be recognized that the numbers of people noted in the chart are just a small fraction of the total numbers of people adversely affected by ozone air pollution who will be helped by the proposed new standard, once the myriad of other adverse health effects and other locations throughout the U.S. that are presently out-of-compliance with the proposed ozone standard are considered.

In order to give the sub-committee some insight as to the huge numbers of other effects lurking beneath the surface of the table presented, I have made working estimates of the other documented adverse impacts of ozone exposure that will also be reduced in New York City, once the new standard is met.

The results of my analysis are presented in the attached figure entitled the "Pyramid of Annual New York City Adverse Impacts of Ozone Avoided by the Implementation of the Proposed New Standard (vs. "As Is"). This pyramid is intended to be illustrative of the enormous gaps in the table presented at the hearing, and is not presented as a peer-reviewed comprehensive documentation of all the benefits which would be accrued by achieving the EPA's proposed new standard. Please note that the figure could not be drawn "to scale". If it were drawn "to scale", the New York City asthma admissions triangle would not even be visible, since it accounts for only 0.01 percent of the total number of ozone related impacts noted. However, despite the fact that it visually overstates the relative size of the NYC hospital asthma admissions, and the fact that many ozone effects cannot be considered in these calculations due to a lack of data, this figure still makes very clear that the New York City asthma admissions counts considered in the table presented at the hearings represent only a small fraction (far less than 1 percent) of the adverse effects of air pollution which will be avoided through the implementation of the new standard being proposed by the EPA.

Pyramid of New York City, NY Annual Adverse Ozone Impacts Avoided By The Implementation of The Proposed New Standard (vs. "As Is")*



*Figure section sizes not drawn to scale.

The starting point of the analysis I used to estimate the “pyramid” of effects noted in the attached figure is the 265 New York City asthma admissions that will be avoided as a result of the implementation of the new standard, as quoted by Senator Chafee from top line of the chart (i.e., $385-120 = 265$ admissions). First, as I noted in my written testimony, there are also non-asthma respiratory admissions effects. Based upon the average ozone impacts derived from my ozone-admissions regression results for New York City and Buffalo, this indicates that the non-asthma respiratory admissions avoided (for causes such as pneumonia and bronchitis) are about 90 percent of the size of the asthma admissions, or 240/yr. Now, based on the fact that New York City hospital records indicate that 12.6 percent of pediatric asthma emergency department (ED) visits result in an asthma hospital admission (Barton et al, 1993), it is estimated that the ED visits associated with the 505 ozone-related respiratory admissions would amount to approximately 3,500 ozone-induced ED visits (i.e., $505 \times 1/126$). Furthermore, using the ozone adverse health effect coefficients derived from the published literature by the Empire State Electric Energy Research Corporation (ESEERCO) in the New York State Environmental Externalities Cost Study (Oceana Publications, Inc., December, 1995), and ratioing the ozone effect coefficients provided in that report with that for asthma hospital admissions in New York City (used to get the 265 admissions), effects for other outcomes were derived, based on the original 265 NYC hospital admissions/day estimate. In this way, estimated annual effects to be avoided in New York City each year were also derived for:

- acute (i.e., daily) mortality,
- asthma attacks,
- Restricted Activity Days (i.e., the total number of person-days during which some normal activities were curtailed), and
- Acute Respiratory Symptom Days (i.e., the total number of person-days during which additional respiratory symptoms would be experienced).

Some may quarrel with the specific coefficients chosen here to model the other effects, but the point remains that these other effects collectively represent huge multiples of the hospital admissions benefits noted for New York City in the chart presented at the hearing. Moreover, the categories of effects considered in the attached figure are not exhaustive by any means, but they still serve to show that the table presented at the hearings grossly underestimates the number of adverse health events that can be avoided by the meeting the proposed standard.

Note that the numbers in this figure have been corrected to avoid double counting of adverse health “events”. For example, the number of hospital admissions has been subtracted from the total number emergency department visits, assuming that the patients would have first passed through the ED before being admitted.

Note also that this figure can be used to consider other cases in the hearing chart as well, since all estimates have been scaled to the asthma admissions number. For example, for the difference between the existing and the proposed new standard cases, the numbers in this figure would all be divided by three ($= (210-120)/(385-120) = 90/265$). However, this calculation underestimates the benefits of the new standard, since it fails to account for the more rapid progress which will no doubt be able to be achieved in New York City under the new standard, when upwind counties cleanup. The comparison to the “as is” case contained in the attached figure is the more apt comparison.

(ii) By using the New York City year-round counts of asthma admissions (28,470) as the denominator in its percentage ozone effect calculations, even though elevated ozone occurs predominantly during the summer months in that city, the chart provides percentage changes in admissions to be achieved by the control of ozone which may be misleading. Indeed, during the months of my study in New York City (June, July, and August) upon which the estimates in the table are based, the total asthma admissions were only 4,545 (averaged over the two summers). Since most of the effects noted by the EPA risk assessment would happen during these summer months, a more relevant estimate of the percentage reductions achieved would therefore be approximately $28,470/4,545$ 6 times as large as indicated by the chart presented at the hearing.

Thus, again, the information provided in the chart presented at the hearing understates the health benefits which will be achieved by the implementation of EPA’s proposed revision to the ozone standard.

(iii) Senator Chafee’s remark during the hearing that this chart suggests to him that “we are dealing in very, very minor improvements to the health of the citizens of New York City” indicates to me that the numbers in this narrowly focused chart are being overinterpreted and overemphasized. The chart represents an analysis of only a single adverse health outcome, in a single city, from a single study, selected from an entire body of hundreds of studies of a wide range of adverse effects that

result from exposures to ozone air pollution that have been considered by the EPA in setting the newly proposed standard.

Just as the U.S. EPA could not propose an ozone standard to the American people based on a single study of a single outcome in a single city, no matter how excellent that study, neither should we rush to judgment of the EPA's proposed standard on such a slender basis. The entire body of evidence available, including that in the EPA CD and Staff Paper and that presented by witnesses at the EPA public hearings, should be weighed before reaching a judgment on the appropriateness of the EPA proposal.

Question 2. One of the arguments for not setting a tougher ozone standard is that, while air pollution is dropping, the incidence of respiratory disease is increasing. If this is true, then air pollution is not causing respiratory disease. What is your response to this?

Response. While this argument sounds logical on the face of it, this is not a correct conclusion. That is because the increase in asthma incidence over the last decade was driven by an unprecedented increase in the underlying prevalence of asthma (the number of persons having asthma). According to the National Institutes of Health National Asthma Education Program, the number of persons in the U.S. with asthma rose by 29 percent between 1980 and 1987. In the face of this growth in the prevalence of asthma, the reduction in asthma attacks achieved by the modest reductions in the average ozone levels we have been able to achieve in the U.S. in recent years (only 7 percent between 1985 and 1995, according to the EPA), could not possibly offset the dramatic increase in the numbers of new people with asthma. Thus, the overall incidence of asthma problems has risen, despite our efforts to reduce ozone air pollution and its adverse effects on asthmatics.

Probably the most important thing to derive from this discussion, however, is that, as the prevalence of asthma rises in our population, then there are more and more people outdoors in the summertime who are at risk of adverse impacts from ozone air pollution. Unfortunately, most of the factors that aggravate the lungs of those with asthma and induce asthma attacks cannot be controlled (such as attacks due to breathing cold air), but ozone is one of the few known important asthma triggers which we can as a Nation do something to control. This makes it all the more imperative that we move forward with EPA's proposed strengthening of the ozone air quality standard.

RESPONSE OF DR. THURSTON TO AN ADDITIONAL QUESTION FROM SENATOR BAUCUS

Question. One of your studies focused on the impacts of ozone on asthmatics. Your Table VI-2 (revised) indicated the number of hospitalizations of asthmatics in New York City that would be prevented by the implementation of the proposed new ozone standard. Is this chart sufficiently indicative of the number of serious health effects that would be avoided by implementation of the proposed standards? If not, would you explain what other health effects would likely be avoided and the relative number of people at risk?

Response. First of all, let me clarify that the chart in question, Table VI-2 (revised), while utilizing the results of a study I conducted and published, is not my work. The chart was developed from work done by the U.S. EPA, and is presented in the OAQPS Ozone Staff Paper (EPA-452/R-96-007).

The chart is not sufficiently indicative of the number of serious health effects that would be avoided by the implementation of the EPA's proposed new standard. Nor was it ever intended to be interpreted as such by the U.S. EPA. Taken out of the context of the EPA report's purpose, this chart grossly underrepresents the health benefits which will be accrued to the American people as a result of the implementation of the EPA's proposal.

As I detail in my response to Senator Lieberman's written question, there are many significant adverse health impacts occurring throughout the U.S. today as a result of ozone air pollution that not considered by this table. These include hospital emergency department visits, asthma attacks, emergency visits to private physicians, increased asthma medication use, restricted activity days (e.g., work days lost), more frequent respiratory symptoms, reduced lung function, and diminished quality of life (e.g., due to reduced ability to walk up stairs, etc.). For example, available studies indicate that, for every one ozone induced asthma hospital admission, there are another 7 persons who became ill enough because of ozone to require a visit to the hospital emergency department (ED), and some 700 asthma attacks because of ozone. Clearly, asthma hospital admissions resulting from ambient ozone, while representing a severe and important health impact, are near the tip of an "iceberg" of adverse health effects and health care costs being borne by the American

people every summer, and which will be largely avoided if the EPA's proposal is allowed to be implemented.

Indeed, as presented in my response to Senator Lieberman, when one broadens the scope of the chart to include the other documented health impacts of ozone exposure, and then more realistically calculates the total numbers of cases of adverse health effects, the asthma hospital admissions noted in Table VI-2 (revised) represent only 0.01 percent of the effects that will be avoided in New York City by the implementation of the EPA proposal.

RESPONSE OF DR. THURSTON TO AN ADDITIONAL QUESTION FROM SENATOR INHOFE

Question. In the hearing, you stated that you took personal income into account in your Canadian studies. How was this accomplished? Did you control for income variances by determining the mean income level for hospital admissions, or by some other method? How did you obtain this income information, through personal interviews or hospital records?

Response. Because of the time-series design of our Toronto study, it was not necessary to actively control for income level, since events in a single population were being compared over time, rather than an intercomparison of different populations. Because an individual's wealth category does not vary from day-to-day the way that air pollution levels do, it is not necessary to control for this factor in such time-series studies. By following the same group of people over time, this factor is inherently controlled for by the study design.

In contrast, it is desirable to control for such factors in a cross-sectional study, which intercompares different populations at one time, with the various populations potentially having differing characteristics. An example is the cross-sectional study that Dr. Haluk Ozkaynak and I conducted when I was a Research Fellow at the Kennedy School of Government at Harvard University, and that was published in the journal *Risk Analysis* in 1987 (Volume 7(4): pp. 449-461). This study compared city-to-city variations across the U.S. in annual mortality versus variations in annual average air pollution across these same cities, during the year 1980. In this case, we addressed city-to-city variations in economic characteristics using two indices of wealth: the percent of the population living below the poverty level in each city, and the percent of the population with a college degree in each city. After statistically controlling for these and other socio-economic factors across cities, we found that PM_{2.5} particles (those less than 2.5 micrometers in diameter) were contributing significantly to the annual mortality of Americans, accounting for between 3 and 8 percent of all deaths at that time (from 60,000 to 160,000 deaths per year). Our results also indicated that particles larger than 2.5 micrometers did not contribute significantly to these mortality impacts. This is consistent with the Toronto study you mention, which also found that particles larger than 2.5 micrometers in diameter did not significantly contribute to the adverse health effects found for fine particles (in this case, increased hospital admissions). Hence, both of these studies support the need for the U.S. EPA to move from the present PM₁₀ standard to a PM_{2.5} standard.

It is also pertinent to this information-gathering hearing to mention that, in the U.S. cross-sectional mortality study, we also looked at the fine particle mass as a function of source category (using elemental tracers of various pollution source categories), finding that particles from the metals industry (such as the iron and steel industry) and from the burning of coal (such as from coal-fired powered plants) were indicated to be the most significant contributors to the mortality impacts of fine particulate matter.

PREPARED STATEMENT OF DR. DANIEL B. MENZEL, PROFESSOR, DEPARTMENT OF COMMUNITY AND ENVIRONMENTAL MEDICINE, UNIVERSITY OF CALIFORNIA

My name is Daniel B. Menzel. I am professor and chair of the Department of Community and Environmental Medicine, University of California at Irvine, Irvine, CA. I have had more than 30 years experience in research in air pollution and toxicology. My expertise centers in two areas: mechanisms of air pollution toxicity and mathematical modeling of toxicology, particularly deposition of air pollutants in the respiratory tract. I have served as a senior author on multiple EPA Criteria Documents and recently as a Consultant to the Clean Air Scientific Advisory Committee examining the Particulate Matter Criteria Document and proposed standard.

The committee has requested that I provide my views on the ozone and particulate matter standards, which EPA has published in the Federal Register and intends to implement under the Clean Air Act. I am pleased to do that and would

also like to extend my testimony to include the research effort of EPA because it directly affects the standard-setting process. I understand that the two standards present different problems in terms of the form of the standard, the scientific data supporting each standard and the process by which the standard was promulgated. In my view, however, there are similarities between the two standards that reflect a major deficiency in EPA's efforts. The common deficiency is the lack of solid scientific data. EPA is a grossly underfunded Agency given the scope of its responsibilities. EPA has not done well with its resources by not sustaining research to meet the long-term goals of the Agency. Thus, I hope that the committee will allow me to express my concerns about the research planning at EPA.

AIR POLLUTION IS A MAJOR LONG TERM PUBLIC HEALTH PROBLEM

Air pollution is a worldwide problem. In the United States air pollution is of such public health importance that it is critical that a national debate be undertaken on the future directions of air pollution research and regulation. This committee is providing a very valuable forum to the people so that they may learn more about the scientific controversy surrounding these two air pollutants and the alternative views that exist concerning the future of air pollution remediation efforts. I am at the moment writing a review of the toxicology of ozone.¹ This will be the third review of ozone that I have written for the scientific literature. Almost 10 years have elapsed since my last effort, and I was surprised and saddened to note on examining the literature that questions which we raised in the review in 1988 still remain unresolved. Much new human data has become available on ozone supporting a lower standard and shorter averaging time, but the book is far from closed on ozone. I also wrote the first part of the health section of the SO_x (sulfur oxides) Particulate Matter Criteria Document for EPA in 1980. Many of the questions raised in that document also remain unanswered. As a consultant to the Clean Air Scientific Advisory Committee I assisted in the review of the current Particulate Matter Criteria Document. Not only were the fundamental questions raised in the original SO_x Particulate Matter Criteria Document still existent, but new important questions arose for which we have no answer. All of these experiences suggest to me that a greatly enhanced and invigorated research effort in air pollution is needed if we are to make sound, reasonable and rational decisions on the implementation of clean air standards. If anything, air pollution research is now more important to the national public health than ever before.

Both the ozone and particulate matter standards have vast implications for the quality of life and the economy of the United States. It is my opinion that the vast majority of Americans support improving and enhancing the quality of their life by eliminating or decreasing air pollution. Americans are quite willing to shoulder the burden of cleaner air, cleaner water, and cleaner food if they can understand clearly the benefits to be gained by these activities. The confidence of the American people in the decisions being made on environmental issues is critical to the ability of this government to govern and implement these decisions. If ever the public loses confidence in the environmental strategies promulgated by the Federal Government then it will be impossible to carry out large national programs designed to eliminate or at least ameliorate the adverse effects of air pollution. I am very concerned that the Environmental Protection Agency and the Congress maintain the confidence of the U.S. public and demonstrate to the public their vigorous support for a better quality of life and clean air. Scientific truth is the only lasting commodity upon which decisions can be based.

GENERIC ISSUES

From my view the difficulties that we face with both the ozone and the particulate matter standard stem from generic issues in toxicology which must be addressed in a sound scientific manner. The first of these generic issues is a plausible biological mechanism of action for the particular pollutant. The second is the nature of the dose response relationship. I will address each of these and give examples of how they impinge upon the two standards that we are discussing today.

Plausible Biological Mechanisms

What is a plausible mechanism? We have learned a great deal about the quantitative nature of toxic reactions in the last 40 years. It is now possible to divide biological reactions to toxicants into several categories under which plausible mech-

¹ Shoaf C.R. and Menzel, D.B. Oxidative damage and toxicity of environmental pollutants. In: Cellular Antioxidant Defense Mechanisms. (ed., C. K. Chow) CRC Press, Inc, Vol. 1:197-213, 1988.

anisms have been elucidated. A plausible mechanism of action for a toxin places the toxin within the context of our knowledge of disease processes. Having a plausible mechanism of action increases our confidence that health effects observed in animals will occur in humans. Understanding a mechanism of action also makes experiments more meaningful and relevant. In this forum it is not possible for me to elaborate in greater technical detail on how a plausible mechanism influences the experimental design and interpretation of the results of experiments. Experimental design and the concept of plausible mechanism of action are dealt with in standard textbooks of toxicology, such as "Cassaret and Doull's Fundamentals of Toxicology".

A plausible mechanism of action is critically essential to controlled human exposure studies. The extrapolation from animal experiments to human exposures as they occur in nature, that is with free-living people, depends upon an intermediate link of controlled exposures of human volunteers to the toxin. We must have a clear idea of a plausible mechanism so that human studies can be developed with due care that no harm will ever result to the volunteers who courageously commit themselves to these kinds of experiments. In air pollution many of the human studies have been very limited because of the lack of a clear understanding of a plausible mechanism. Investigators have been very reluctant to engage in high level exposures of human subjects because they fear that some long-term harm will result from their experiments. Clearly, we cannot and will not tolerate human experimental studies that result in harm to the volunteer. This is simply not ethically acceptable.

Plausible Mechanism of Ozone Toxicity

One plausible mechanism of action of ozone is the production of free radicals by the reaction of ozone with cellular constituents. The free radical theory is that which we proposed in 1971.² It is now clear that this mechanism of action is too naive and simplistic and clearly does not explain the consequences of chronic exposure to ozone. Studies with experimental animals clearly show that the results of a continuous or intermittent lifetime exposure to ozone are highly complex and are not predictable from the free radical hypothesis alone. Further experiments are needed with life-term exposures of experimental animals using the most modern molecular biology techniques. The complex pattern of lifetime ozone exposure must involve multiple signal transduction pathways. Simply put, the adverse health effects of chronic exposure to ozone are complex and beyond the free radical theory which we now recognize as accounting for the brief initial contact of ozone with the lung.

Chronic exposure is the critical issue in ozone exposure. EPA initiated and was carrying out an excellently conceived and implemented research program on the chronic effects of ozone in support of the current ozone standard. But this research has stopped and support for ozone research by other Federal agencies has stalled. Basic research support for ozone by the National Institutes of Health and particularly the National Institute of Environmental Health Sciences (NIEHS), has fallen away. The scientific community is in error in allowing this to have happened.

Very compelling controlled human exposure experiments suggest that the current ozone standard (0.12 ppm) may be toxic. The short term exposures under which humans can be safely exposed does not allow us to study the chronic effects of ozone exposure. Epidemiologic studies are underway in the South Coast Air Basin, particularly those by Professor John Peters of the University of Southern California but this study is hampered because no quantitative biomarker of ozone health effects has been developed.

We would not be sitting here and engaging in this discussion if EPA's chronic ozone study in experimental animals had been carried out. Nor would we still have doubts about the ozone standard if ozone research had received a high priority in research support by the other Federal research agencies such as NIH and NSF.

In summary, there is a preliminary biologically plausible mechanism of action for ozone. The free radical theory is not comprehensive and does not explain all of the effects of chronic exposure to ozone. Much additional work is needed to understand the chronic effects of ozone.

Particulate Matter

In contrast to the ozone problem, no plausible biological mechanism of action has so far been proposed for particulate matter. It has been very difficult to demonstrate toxicity for particulate matter in experimental animals. In my laboratory and that of my colleagues at UCI we have not been able to show major toxicity with particu-

²Roehm, J.N., Hadley, J.G. and Menzel, D.B. Oxidation of Unsaturated Fatty Acids by Ozone and Nitrogen Dioxide: A Common Mechanism of Action. *Arch. Environ. Health*, 23:142-148 1971.

late matter at potencies approaching the levels reported from epidemiologic studies.^{3,4}

To place this problem in a more global context, urban particulate matter is a universal problem. Particulate matter seems to be a common result of human concentration in urban areas. To eliminate all of the particulate matter in our cities would, in my view, be only possible by the elimination of all human activity. Clearly this Draconian approach is not reasonable.

The studies of Schwartz and his colleagues^{3,4} have challenged our conclusions from experimental animal studies. These studies indicate that all particles regardless of their geographic origin have the same toxicity. It is well known that the chemical composition of the urban particles differ widely between geographic areas. For example, in the western US, especially in the South Coast Air Basin of Los Angeles and its environs, the chemical processes responsible for the formation of particulate matter depend on photochemical reactions. Nitric acid is the dominant end product. There are very few oxides of sulfur present because of the nature of the fossil fuels used in California. On the other hand, in the East Coast Corridor the consumption of sulfur-containing fuels is much greater, and the chemistry of the reactions leading to the formation of particulate matter is not as dependent upon photochemistry as it is upon chemical reactions. Sulfuric acid, not nitric acid, is the dominant end product present in particulate matter. The chemical nature of the particles formed in California are quite different those of the East Coast Corridor. Yet the health effects measured by epidemiologic techniques suggests that all particles have the same effect despite the differences in chemical composition. This is a very troublesome problem. One of the basic tenets of toxicology is that the toxicity occurs via chemical reaction. How then can the same effect result from very different kinds of chemistries? We must conclude that there is no plausible mechanism now available for particulate matter which can account for the reported results.

Particle Size and Site of Action of Respirable Urban Particles

The toxicity of particles also depends on the site within the respiratory tract where they are deposited. A major advance has been the recognition of the dependence of toxicity on the site of deposition. The site of deposition in the respiratory tract depends, in turn, on the physical size of the particle. By measuring the amount of particles within the size range which can be deposited in the human lung, EPA adopted a biologically based criterion for its standard setting. This concept of defining particulate air pollution in terms of the size of particles most likely to be responsible for the adverse health effects is referred to as PM₁₀ where 10 refers to particles of 10 micrometers aerodynamic mass median diameter or less. PM₁₀ is a fairly good surrogate measurement for the amount of material that would actually be inhaled and deposited in the human respiratory tract. Schwartz and his colleagues extrapolated from measured PM₁₀ values. PM₁₀ is a major advance in public health policy pioneered by EPA. The PM₁₀ concept shifts emphasis to particles of that size which are likely to be the most harmful to people. A network of PM₁₀ monitors has been constructed in the US and large amounts of data have been accumulated.

Schwartz and his colleagues went beyond PM₁₀ and extrapolated from a very limited set of measurements of PM_{2.5} and PM₁₀ to estimate PM_{2.5} values and to relate mortality and morbidity to particulate matter exposure smaller than PM₁₀ or particles less than 2.5 micrometers mass median aerodynamic diameter. Only a few data exist on the PM_{2.5} exposure in our major cities. By shifting from PM₁₀ to PM_{2.5} values, a major difference in the regional deposition within the lung of these particles is suggested as the site of action. The smaller the particle the more deposition occurs in the deeper parts of the lung. By assigning toxicity to particles in the PM_{2.5} range the site of action is also assigned to the thoracic region of the lung. Because these PM_{2.5} values are calculated and not measured, it is very difficult to place the heavy weight of evidence on this ultrafine particle range as EPA has done in its criteria document. Even with a shift in attention to particles of this size range, there is still no plausible mechanism for toxicity. Further, some of the CASAC members questioned the potency of the particles calculated from the mortality and mobility data. All of this underscores the importance of the research program reviewed by CASAC as part of the particulate matter standard setting process.

³Saldiva, P. H., Pope, C. A., Schwartz, J., Dockery, D. W., Lichtenfels, A. J., Salge, J. M., Barone, I. & Bohm, G. M. (1995) Air pollution and mortality in elderly people: a time-series study in Sao Paulo, Brazil. *Arch. Environ. Health* 50:159-163.

⁴Schwartz, J. (1995) Short term fluctuations in air pollution and hospital admissions of the elderly for respiratory disease. *Thorax* 50: 531-538.

DOSE RESPONSE RELATIONSHIP

The dose response relationship is a curve that relates the number of individuals responding with an adverse reaction (mortality, morbidity or the like) to a certain exposure concentration of the chemical. The shape of the dose response curve is important when setting standards. All theories of the dose response relationship so far indicate that these curves will be non-linear; that is, there will be a point at which the probability that a response would occur is very unlikely. To put it another way, all theories suggest that there is a concentration at which nothing will occur while above that concentration adverse effects will occur. The point at which there is nothing detectable is the threshold. The dose-response relationship is at the heart of the risk assessment. In both the particulate matter and ozone standard the dose-response relationship is only poorly understood. Consequently, estimates of risk are also uncertain. Examples for ozone and particulate matter follow.

The Particulate Matter Dose Response Curve Is Linear Not Curved

The current assumption of epidemiologic studies is that the mortality or morbidity is a linear function passing through zero at zero concentration of particles. The dose-response function has no point at which no adverse effects occur. The linear dose-response curve is in opposition to all of the theories and experimental data derived for a host of chemicals acting by a variety of different mechanisms of action.

The epidemiologic basis for a linear relationship between effect and dose is very poor. The data are not supported by any kind of a generalized theory and are in many cases a default assumption coming about because the epidemiologic data are weak. It is very difficult for epidemiologists to relate exposure to effect. The methodologies of epidemiology at present are insensitive to the concentration or exposure effect. This is especially true in ecological studies where indirect evidence is used for adverse health effect.

For example, the epidemiologic studies of particulate matter health effects depend upon death certificates and the coincidence of an increase in death with an increase in particulate matter exposure. These studies again provide no indication of how a person might have died from the exposure to particulate matter. The studies only associate the death with the exposure to particulate matter. Nonetheless, the increases in mortality associated with particulate matter are troublesome. If the magnitude of mortality suggested by these studies is correct, then we are faced with a major public health problem that demands immediate attention.

Time and Intensity Relationships in Ozone Health Effects

EPA initiated a time and intensity study in cooperation with the USSR. This program was well thought out and attacked the question of which variable is most important in determining the health effects of ozone. From the data that were generated by this study it appears that the intensity is the most critical factor rather than the duration of exposure for ozone toxicity. These studies of the time and concentration effects on ozone toxicity led to the current hypothesis upon which the proposed ozone standard is based. If it is correct that the magnitude of the exposure is more important, then extremes of exposure should be reduced. One strategy to reduce exposure to extreme concentrations of ozone is to change the averaging time for the standard, making implementation plans stricter for short-term excursions. The US-USSR research program to study the time and concentration dependency of ozone adverse health effects was very productive and was progressing along a track which would, if continued, have provided us a great deal of information at this time. Unfortunately, EPA chose to reduce and essentially eliminate this line of study. Extramural support for the program lagged and ozone in general has become an unpopular topic for support by other government agencies such as NIEHS.

Based on the fragmentary information that we have available, I feel that it is appropriate to support the EPA proposal of changing the averaging time for the ozone standard so that large excursions over short time periods will be eliminated or reduced. However, one should recognize that changing the averaging time will have a major impact on State implementation plans and will have major economic consequences. Clearly, understanding the nature of the dose-response relationship is very important and affects which alternatives we choose to reduce ozone health effects.

Time and Intensity Relationship for Particulate Matter Health Effects Are Unknown

As stated above, most time and intensity (dose and dose-rate) relationships for chemicals follow a simple relationship that the product of the dose rate and the time of exposure form a constant. This constant is arbitrary and unique for each chemical. Epidemiologic studies of the increases in mortality associated with increases in particulate matter are strictly linear with the amount of particulate matter. One reason

way this assumption occurs is that a lag period has been assumed. The lag period means that the increase in mortality occurring 2 to 3 days after an exposure are related to the exposure to particulate matter, not earlier or later. The underlying hypothesis is that particulate matter toxicity is not immediately evident but occurs after this lag period. This very short acting time raises the question as to what happens when people are exposed to concentrations of particulate matter over the long term. We really have no data on the chronic effects in humans of exposure to particulate matter. Chronic exposure studies are very difficult to achieve using epidemiologic data.

To my knowledge there are no experimental animal data or controlled human studies which relate this kind of lag time to exposure to the toxicity of particulate matter. In my laboratory and that of my colleagues at UCI we have found that experimental animals such as the rat are very insensitive to particulate matter exposures. We have never observed potencies equivalent to that proposed for humans based on the epidemiologic data. This again raises the question of a plausible biological mechanism of action.

THE RESEARCH AGENDA

It is difficult for scientists such as myself whose livelihood depends on experimental research to stand before you and justify additional research without seeming to be self-serving. A careful study, however, of EPA's support of research in the past is related to the missing data in the standard setting process. Sadly, we would not be sitting before you if there had been a steady progression of air pollution health effects research. EPA's research strategy has been to ignore problems until the standard setting cycle is near. Then a massive effort is mounted which is expected over 2 or 3 years to result in sufficient data to solve the research needs. Regrettably we have seen that this strategy does not work. The same questions recur from criteria document to criteria document. There are just not enough resources put into air pollution health effects research so that we are really certain what we're about.

It is also my opinion that this problem also appears in the low esteem with which Congress holds EPA research. I am acutely aware that one Congress cannot obligate another Congress and that this independence of one Congress from another is fundamental to the development of our country. But I think it is time that the Congress in its wisdom faced up to the need to make its desire known to its successors that support of research for long-term problems in all areas of health is essential.

Air pollution is a long-term problem. From my observations and the data in the literature there is no urban area which does not have air pollution. We are still dependent on the consumption of fossil fuels for energy and the prospects of independence from fossil fuels are far into the future. My colleague, F. Sherwood Rowland, received the Nobel Prize in Chemistry for his contributions to the global problem of depletion of the ozone layer. Dr. Rowland's contributions clearly show that this air pollution problem is global. He also was able with his colleagues to demonstrate that this was a long-term process. I see no way that this is not also true for other kinds of air pollution problems.

As I mentioned above in my current review of the literature of ozone I found very little progress had been attained in ozone research over the last 10 years. It is essential then that the Congress mandate to EPA a sustained basic research effort. Only if EPA clearly is committed to a long-term research effort will we solve the problems that still exist today as they existed 10 years ago.

In addition, the Congress should resist any rush to judgment. I am deeply concerned over the effects of particulate matter exposure as currently revealed by epidemiologic studies. Similarly, I am concerned that we have not demonstrated an important increase in a health benefit from a small decrease in ozone concentration. Both of these alternatives however, are significant commitments on the part of society to change the underlying causes of both ozone and particulate matter generation in our cities. It is my firm opinion that the U.S. public would be willing to engage in whatever is necessary, but they will not support any arbitrary change that results in a significant economic and personal commitment.

Our experience in science policy clearly shows that the U.S. Government is capable of mounting major efforts to solve major problems. No one could have predicted just 5 years ago the remarkable success which is being achieved in AIDS treatment. There is a similar likelihood that a large-scale problem such as air pollution could be better defined and directions for engineering applications clearly delineated if we understood more about the biologic aspects of this problem. Inventorying pollutants in the atmosphere is undoubtedly an important issue, but it does us no good to inventory these pollutants in the atmosphere and yet not have a clue as to what their biologic activity is. I may sound arbitrary in my opinion that we are in a state of

great ignorance, but I think that once you listen to the testimony of my colleagues here you will come to the regrettable conclusion that I am an optimist. I therefore urge the Senate and this committee to undertake a new direction in the support of research by EPA and by EPA's sister Federal agencies such as the National Institutes of Health and in particular the National Institute of Environmental Health Sciences. These agencies need to be enabled, directed and empowered, indeed mandated, to carry out the long-term large-scale research that is necessary to understand much more fully the effects of air pollution on the U.S. population.

CONCLUSIONS

The Proposed Ozone Standard

It is my opinion that we will have achieved only marginal effects by decreasing the current ambient air quality standards for ozone from 120 parts per billion to 90 parts per billion. The nature of the dose response relationship is such that it may still be at a linear range and thus reduction to much lower levels may be necessary to result in the abolition of detectable health effects from ozone. My colleague, Robert Wolpert, and I published a simple analysis of different kinds of dose response relationships for ozone looking toward this very issue. How much would one have to reduce the ozone concentration in the air in order to be able to find a detectable advance in public health? Because the data are so sparse, a multitude of different kinds of theoretical treatments are possible. None of them, however, are sufficiently sensitive that one could lead to a clear prediction of a health benefit. On the other hand, as I mentioned above, a change in the time constant alone is going to have a great benefit. I endorse EPA's analysis of the time constant and think that EPA's proposal to a change in the averaging time for ozone is likely to be of benefit to the public health.

Still, I think that translating these changes into new State implementation plans may be very difficult. To translate both a change in the concentration, that is the amount of ozone that is permissible in the air and the duration over which it is permissible, will be a very difficult task indeed to implement.

Continued research into the health effects of ozone are urgently needed. Further reductions in the ozone standard may be indicated in the near future. Because of the economic impact of ozone standards and strategies, the highest quality research is needed.

Particulate Matter Standard

As I have said previously, I do not doubt that the particulate matter problem is a very serious problem indeed. We need to place a very strong active and progressive research program into place in order for us to cope with this problem. It is my view that too little is known. In the report of the Clean Air Scientific Advisory Committee to Administrator Carol Browner, the committee pointed out that one of the areas in which additional research should be undertaken is chronic exposure.

I am not in favor of the use of a $PM_{2.5}$ standard. A viable network of monitoring instruments and sound research supports the PM_{10} standard. The $PM_{2.5}$ standard has no background. There is no existing research quality $PM_{2.5}$ network. Without a research quality $PM_{2.5}$ network it is not likely that we will make much progress toward the goal of a new particulate matter standard. We lack information on the actual $PM_{2.5}$ in the atmosphere of our cities. We do not know the duration of exposure of people to $PM_{2.5}$. The chemical nature of the $PM_{2.5}$ fraction is poorly known. We lack a plausible biological mechanism for particulate matter. We do not know if regulation of $PM_{2.5}$ will be of benefit. A strong aggressive long-term research program is essential to address the current data deficiencies if we are to convince people that this is a major problem.

Avoid Mistakes Of The Past

In my comments above I pointed out that the critical data deficiencies for ozone and particulate matter are generic and extend to the other criteria air pollutants. My criticisms of EPA and of the Congress I am sure have not endeared me to either party. My criticisms are also directed to me and my scientific colleagues. It is time that we faced up to the realities of life. Air pollution is here. Air pollution will be with us. Air pollution is a major problem that cannot be solved in 5 years.

EPA needs more resources. All of the health research establishment needs more resources to deal with this particular problem. The strategy adopted by NIH to deal with major health problems such as AIDS and cancer is dependent on ideas generated outside of the government. This is not to say that government researchers are not knowledgeable. Rather it is simply the recognition that there is great diversity in the United States. We have a lot of people working on the same problem, and from this diversity we achieve greatness. The Congress should instruct the Na-

tional Institutes of Environmental Health Sciences, NIEHS, and EPA to place greater emphasis on air pollution, to seek actively support for extramural programs dealing with air pollution, to look for the unique idea to encourage the primary review groups that this is a programmatic area of importance. Last I would respectfully ask that the Congress use the legislative hammer in another way. The Congress can have a major impact on the sustainability of research in this area. Clearly the Senate recognizes that regulation of air pollutants is a major national problem. The Congress should, in my judgment, place a burden on the government agencies to carry out the needed long-term research. In doing so, the Congress has to realize that it has to reallocate resources and that air pollution is a national problem of long-term importance requiring additional support.

Thank you for the opportunity to have addressed you.

PREPARED STATEMENT OF DR. ROGER O. McCLELLAN, PRESIDENT, CHEMICAL
INDUSTRY INSTITUTE OF TOXICOLOGY

Chairmen and distinguished members of the Subcommittee: I am pleased to have this opportunity to testify at your request on scientific issues related to the new National Ambient Air Quality Standards for Ozone and Particulate Matter that the Environmental Protection Agency proposes to promulgate under authority of the Clean Air Act. I request that this written testimony be included in the record as though read in its entirety.

By way of background, I serve as President of the Chemical Industry Institute of Toxicology, a not-for-profit research organization located in Research Triangle Park, North Carolina. The institute is supported principally by some 30 leading industrial firms and has a mission of developing, through the conduct of research, an improved scientific basis for understanding and assessing the human health risks of exposure to chemicals. This mission is being achieved through the conduct of an in-house research program carried out by 160 scientists, postdoctoral fellows, and supporting personnel.

The comments I offer are based on my experience as a scientist concerned with the risks of airborne materials and my extensive service in advisory roles to numerous public and private organizations. (An abbreviated biographical sketch is appended.) My advisory experience has included long-term service on the EPA Science Advisory Board. I have served under each of the Agency's Administrators on a number of committees, previously as chair of its Clean Air Scientific Advisory Committee, Environmental Health Committee, Environmental Radiation Exposure Advisory Committee, and the Research Strategies Advisory Committee and as a member of the Relative Risk Reduction Strategies Committee. Most recently, I have served as a member of the Clean Air Scientific Advisory Committee Panels considering the National Ambient Air Quality Standards for Ozone and Particulate Material. I also served on the CASAC panels that earlier reviewed the scientific basis for the current National Ambient Air Quality Standards for ozone and particulate matter.

LEGISLATIVE BASIS FOR NATIONAL AMBIENT AIR QUALITY STANDARDS

The legislative basis for the Clean Air Act is well known to all of you. However, I would like to highlight several key points to provide a basis for my remarks. The Clean Air Act directs the Administrator of the Environmental Protection Agency to identify pollutants which "may be reasonably anticipated to endanger public health and welfare" and to issue air quality criteria for them. These air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air. . . .

For these "criteria pollutants" the administrator is directed to propose and promulgate "primary" and "secondary" National Ambient Air Quality Standards. In the interest of brevity, I will consider only the primary standard setting process in this testimony. The primary standard is defined in the Act as one "the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria and allowing an adequate margin of safety, [is] requisite to protect the public health." The legislative history of the Clean Air Act indicates that the primary standard is to be set at "the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population" and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group." The standard is viewed as sufficient whenever there is "an absence of adverse effects on the health of a statistically related sample of persons in sensitive groups from exposure to ambient air."

The courts have held that the "margin of safety" requirement for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. And further, it was intended to provide protection against hazards that research has not yet identified or whose medical significance is a matter of disagreement. In setting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degrees of uncertainties that must be addressed. The margin of safety comes into play at the boundary between conclusive evidence of adverse effects related to pollutant exposure and levels of exposure where there is no conclusive evidence of adverse effects with unknown or only partially quantified risks. The selection of a particular approach to providing an adequate margin of safety has been viewed by the courts as a policy choice left specifically to the Administrator's judgment.

The primary standard is to be set without regard to the cost of its implementation.

A section of the Clean Air Act enacted in 1977 requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate. The Act requires that an independent scientific review committee be appointed to "complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate. This function is carried out by the Clean Air Scientific Advisory Committee of EPA's Science Advisory Board.

Put in its simplest form, the Clean Air Act requires the Administrator to develop criteria and promulgate standards for certain air pollutants to protect against adverse effects in the public, including sensitive populations, with an adequate margin of safety. As clearly implied by the statutory language, levels of pollutant exposures can be identified that cause effects, while lower levels of exposure will be without effect (i.e., a threshold for response). A "margin of safety" is then used to select a lower level for the standard, a level that, if attained, should not result in unacceptable risk.

OZONE STANDARD

The current primary NAAQS for ozone is set at 0.120 ppm with a 1-hour averaging time. Attainment of the standard occurs when the expected number of days per calendar year with a maximum hourly average concentration greater than 0.120 is equal or less than one. Operationally, the standard is exceeded if the 0.120 ppm hourly average concentration is exceeded a fourth time in a 3-year period.

In 1993, the EPA Administrator reaffirmed the 0.120 ppm standard with a 1-hour averaging time. At the same time, the Agency initiated the preparation of an updated criteria document on ozone and made plans for preparation of a staff paper for CASAC review of both the criteria document and staff paper. The CASAC came to closure on the criteria document on November 28, 1995 and on the staff paper on November 30, 1995.

The review process for the NAAQS for ozone considered a substantial amount of new data published since the last CASAC review was concluded in early 1989. The data came from four sources; controlled human exposure studies, field studies of children and healthy adults, analysis of air quality data and hospital admissions and laboratory animal studies.

The controlled human exposure studies involved individuals engaged in light to heavy exercise with exposure to ozone over a range of concentrations for 1 to 6.6 hr. Decrements in pulmonary function and increases in symptoms of respiratory responses were exposure concentration and exposure duration dependent. However, there was substantial intergroup variability in response as well interindividual variability for repeated exposures. The results of these studies support the use of an 8-hour averaging time.

The field studies of children in summer camp and exercising adults took advantage of naturally occurring variations in ambient ozone concentrations. Lung function tests were performed in all the individuals. A small, but substantially significant, association between ozone concentrations and reduced pulmonary function was observed for both groups. The relationship between increased ozone and decreased function was approximately linear with no clear threshold for an absence of effect.

The hospital admission studies examined the association between daily ozone concentrations and daily hospital admissions for respiratory effects. Asthmatics were

identified as one susceptible subpopulation. Linear relationships were observed with increasing ozone and increased admissions with no clear evidence of a threshold.

The animals studied revealed effects that were qualitatively similar to those seen in people. The results of a key study with rats and mice exposed 5 days per week to ozone at exposure levels of 0.12 ppm and higher for 2 years suggested that long-term exposure at current ambient concentrations of ozone were unlikely to produce serious, irreversible changes in the lungs. I found those findings reassuring; they reduced my concern for the long-term impact from brief exposures that produce reversible effects. Based on consideration of all of the data, the EPA staff paper recommended consideration of an 8-hour averaging time standard in the range of 0.070 to 0.090 ppm and a potential for multiple exceedances.

Based on the information presented in the ozone criteria document and analyzed in the ozone staff paper, the CASAC reached several key conclusions:

(1) Ozone remains an appropriate indicator for use as an indicator of photochemical oxidants,

(2) An 8-hour averaging time standard was more appropriate for a human health-based standard than a 1-hour average time,

(3) "The weight of the evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure above background concentrations" and, thus, "there is no 'bright line' which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health."

(4) The CASAC Ozone Panel members expressed a range of preferences for the level of the standard.

No. of Panel Members	Preferred Ozone Level (ppm)
1	0.090–0.100
3	0.090
1	0.080–0.090
3	0.080
2	Policy Call

It is my professional judgment that the primary ozone standard should be set at 0.090 ppm with an 8-hour averaging time and the use of the 3-year average of the annual third highest maximum of 8-hour average ozone concentration to evaluate attainment of the standard. I would personally prefer to have some form of averaging of data from multiple monitoring sites, when available, rather than using the highest monitor to determine attainment of the standard. The use of multiple monitors would better reflect population exposure and aggregate public health risk.

My professional opinion on the level and form of the ozone standard was shaped by consideration of data such as that shown in Table 1. This table is based on a study by Thurston et al. (1992) who examined the relationship between ozone levels and hospital admissions. The model assumed ozone effects down to a background level of 0.040 ppm. The first row on the table (Excess Admissions) was prepared by the EPA staff and included in the draft Ozone Staff Paper. It may be noted that the excess admissions for various ozone control scenarios included 210 cases for the present standard to a range of 60 to 240 cases for alternative standards. For comparison the present situation ("as is") is estimated to result in about 400 cases. The five lower rows in the table were prepared by CASAC Panel members. The second row reporting the excess admissions as a percentage change from the present standard at first glance appears to suggest considerable difference between the several options. However, the other rows are worthy of detailed consideration before a final conclusion is drawn.

The third row includes both the excess admissions due to ozone-aggravated asthma above the level of the standard and those cases related to ozone below the level of the standard down to background. The relative effect of the different options now appears to be much less, as seen from examining row 4. Let us now turn our attention to row 5, all asthma admissions, with a baseline of approximately 30,000 cases. When this value is compared with that for the various options, ozone-aggravated asthma admissions clearly represent only a small fraction of the total number of cases and the difference in impact of the various options for the ozone standard is small.

It is especially important to note that 680 asthma admissions per year are attributed to background levels of ozone which is assumed to be 0.040 ppm of ozone.

These calculated cases are a reflection of the linear exposure-response models used to calculate the ozone attributable cases.

The primary public health issue relates to the approximately 30,000 cases of asthma admissions. I can personally identify with these cases since one of my children, who grew up in the clean air of New Mexico, was and is an asthmatic. My firsthand recollection of his suffering from asthma attacks triggered by multiple causes such as animal dander, grass pollens, extreme cold air, and heavy exercise left an imprint on me. As much as anyone, I would like to better understand what causes asthma including the vexing issue of why asthma rates are increasing especially when air quality is improving. I have serious reservations as to the extent to which ozone exposures are a significant contributor to the asthma problem.

Let me hasten to add that the health impacts of ozone are not restricted to effects in asthmatics. However, the table clearly illustrates the importance of considering the estimated impacts of pollutant exposures within the broader context of other risk factors for specific health outcomes. In my opinion, the ultimate concern of society is for the aggregate risks from all causes and how best to achieve an overall reduction.

I am personally a strong advocate of comparative risk analyses such as detailed above to help guide decisions on important societal issues. It is my understanding that the EPA Administrator can use analyses such as this in making decisions on the ozone standard although the Administrator is prohibited from explicitly considering costs of implementing the standard.

Before leaving the ozone issue, let me note that I believe it is unfortunate that the Clean Air Act prohibits the consideration of cost in setting the standard. In my opinion, the best interests of society would be served if attention could be focused on the "best buy" for societal actions that will reduce health risks, including those of ozone. Further reductions in ozone may not be cost-effective relative to other options for reducing risks and improving health.

The explicit consideration of the cost of achieving the various options would be of substantial value in making a decision that is likely to have a multibillion-dollar impact on society.

PARTICULATE MATTER

The current particulate matter standard was promulgated in 1987 when the indicator for particles was changed from Total Suspended Particles (TSP) to PM_{10} , the latter referring to particles with a mean aerodynamic diameter less than $10\mu m$. The 24-hour PM_{10} standard was set at $150\ \mu g/m^3$, with no more than one expected exceedance per year, and the annual PM_{10} standard set at $50\ \mu g/m^3$, expected arithmetic mean. The PM_{10} standard is thought to provide a more health-protection-relevant metric for controlling exposure than the old TSP metric.

The particulate matter National Ambient Air Quality Standard for Particulate Matter is not chemical specific unlike the chemical specific standards for other criteria pollutants and most other substances regulated by the Environmental Protection Agency. The PM standard applies to a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. PM is characterized as to its mass within given size range.

Knowledge of the size and origin of particles is, fundamental to understanding their potential health effects and, ultimately, the establishment of appropriate standards and control strategies. Particles in the atmosphere vary widely as to their size and origin. The smallest particles arise from condensation of vapor and a clustering of individual molecules. These very fine particles grow in size and coagulate in the atmosphere to form fine (or accumulation mode) particles that are typically less than a micrometer in diameter. Other larger or coarse particles typically arise by mechanical processes such as the erosion of soil.

The size of particles influences the dynamics of particles in the atmosphere. The finest particles coagulate to become larger particles. These particles may be removed from the atmosphere by rain. The largest particles may settle out due to gravity. Small and medium size particles may be transported long distance by the wind. As a former resident of Albuquerque, New Mexico, I can recall that in the spring we sometimes had some of Arizona blow through when the winds were from the west and Texas and Oklahoma blow through when the winds were from the east.

Scientists studying particles in the atmosphere have appreciated the need to better understand particle size and this has led to the development of methods for collecting particles and characterizing the particles as to size. Just as size influences how particles behave in the atmosphere, size also influences their potential for being inhaled, deposited in the respiratory tract and causing adverse health effects. The

concern for how particles of different sizes could affect health also influenced the design of air sampling devices.

Some of the conventions for characterizing particles as to their size are illustrated in Figure 1. In particular, note the size fractions designated as (1) Total Suspended Particulates (TSP); (2) Particulate Matter, 10 microns size (PM_{10}); and (3) Particulate Matter, 2.5 micron size

The TSP sample represents essentially all the particles that can be drawn into a high volume sampler. This includes many large, heavy particles that have a very low probability of being inhaled and reaching the lungs. These particles are clearly a nuisance but are not of major health concern.

Recognition that smaller particles that can be inhaled led to the development of methods for collecting smaller particles including the PM_{10} fraction. As an aside, it should be noted that some of the smallest of the coarse mode particles are collected in the $PM_{2.5}$ sample. These are collected with devices that will collect 50 percent of the particles 10 micrometers in aerodynamic diameter. Particles larger than 10 micrometers are collected less efficiently, smaller particles are collected more efficiently. The $PM_{2.5}$ fraction is similar except the cutoff is set at 2.5 micrometers.

In 1979–1980 EPA was struggling with the issue of developing a size-selective PM NAAQS to replace the TSP standard set in 1971. Several different size cuts were under consideration and there was a flurry of activity to gather field data using new devices including some calibrated for PM_{15} , PM_{10} , and $PM_{2.5}$. However, the debate was largely removed from EPA's regulatory agency in 1981 when the International Standards Organization adopted a 10 micrometer cut point for particles that could penetrate to the human thorax (i.e., the trachea, conducting, and pulmonary airways). This focused attention on a PM_{10} standard which was formally promulgated in 1987. With promulgation of the of the new standard and the need to demonstrate regulatory compliance, there was a general shift to PM_{10} measurements. TSP measurements were discontinued and, unfortunately, so were most measurements of $PM_{2.5}$. I have termed this phenomena "looking under the regulatory lamp post." In general, after closure on the PM criteria document and staff paper in 1986, the level of financial support for research on PM dwindled.

In my opinion, the Agency took appropriate action to move to a PM_{10} indicator in 1987. The use of the PM_{10} indicator has been effective in guiding actions to control particulate air pollution and minimize the likelihood of adverse health effects attributable to particulate air pollution. From 1988 to 1995 there has been a 22 percent reduction in the annual mean PM_{10} concentrations (see the EPA National Air Quality and Emissions Trends Report, 1995). This and a companion document, National Air Pollutant Emission Trends, 1990–1994 are excellent references for gaining an appreciation of the substantial progress being made in improving air quality in the United States. Unfortunately, detailed data are not available on trends in $PM_{2.5}$ and $PM_{1.0}$ measurements. However, I suspect substantial reductions have also occurred in the concentrations of these smaller particles.

During the early 1990's reports begun to appear in the literature of time series analyses of PM measurements and daily mortality. These were retrospective, opportunistic studies of data collected for other purposes. These studies frequently used techniques developed originally for econometric analyses. The techniques used attempted to account for or filter out effects such as season of year, temperature, etc., that could influence mortality with the remaining statistical relationship between daily PM and daily mortality quantified. Later studies attempted to take account of the role of other pollutants such as ozone and acid sulfates. A major handicap to the conduct of many of these studies was the lack of PM_{10} data. In many cases, the best available data were for TSP. These were then converted or extrapolated to PM_{10} values or, in some cases, even extrapolated to $PM_{2.5}$ values. On average the investigators found about a 4 percent increase in daily mortality for a $50 \mu\text{g}/\text{m}^3$ increase in PM_{10} concentration or extrapolated PM_{10} values.

Unfortunately, only a very few long-term prospective studies of cohorts of individuals have been conducted with associated measurements of PM and other pollutants. Only rarely have long-term multiyear studies been conducted with research quality air pollution measurements made rather than depending on regulatory compliance measurements. The result is excessive dependence on the old TSP measurements or more recently PM_{10} measurements. Only very limited research has been done when both PM_{10} and $PM_{2.5}$ have been measured and only very recently have some $PM_{1.0}$ measurements been obtained. In the cohort studies mortality rates after adjustment for smoking and other confounding variables have been related to the PM_{10} or $PM_{2.5}$ measurements or extrapolated values. EPA used the mortality estimates from two such prospective studies to conclude that there are premature deaths due to chronic exposure to PM.

In my opinion, the EPA staff and consulting scientists assisting the Agency did an admirable job of compiling all that is currently known about the health effects of PM. Unfortunately, the price must now be paid for inadequate support of research on the effects of air pollution. The data base available today is not sufficient to establish a new PM indicator, nor select the level and fond of a new standard.

The data suggest that high levels of PM as experienced in the past are associated with increased morbidity and mortality. However, I must note that some investigators have suggested that the effect measured is a general air pollution effect with PM measurements serving as a surrogate measure of air pollution rather than as a causative agent. The data are reasonably strong for PM₁₀. Unfortunately, the dearth of PM_{2.5} measurements serve as a serious obstacle to rigorously evaluating the association between PM_{2.5} and multiple measures of health for specific populations including those that might be especially susceptible. And we have no evaluations of possible association health indices and other PM metrics such as PM_{1.0} (that would more accurately reflect particles that have been recently formed) or particle size and chemical specific metrics traceable to specific types of sources. An absence of data on other plausible alternatives and the bright light of the regulatory lamp-post keeps drawing us back to evaluating associations with PM₁₀ and to a lesser extent, PM_{2.5}. It has been argued that the only way to get funding for more PM_{2.5} measurements is to get a PM_{2.5} standard. Thus, we are faced with the perverse situation of creating a standard to get scientific data rather than having a standard developed based on solid scientific data. Limited data recently obtained on PM₁₀, PM_{2.5}, and PM_{1.0} size fractions suggest that EPA may be making a serious error in proposing a PM_{2.5} standard to control health risks related to fine particles. In the western United States where PM_{2.5} measurements include substantial soil dust, the use of a PM_{2.5} indicator may lead to exaggerated estimates of risk. These data strongly suggest that a PM_{1.0} indicator may be more appropriate than the use of a PM_{2.5} indicator.

The serious shortcomings in the scientific data on PM_{2.5} and on PM_{1.0} led me to not support the promulgation of either an annual or a 24-hour PM_{2.5} standard. I reluctantly noted that if EPA was going to propose a PM_{2.5} standard, I would set the 24-hour standard at 75 µg/m³ and an annual standard at 25 µg/m³. These would represent levels that would likely not result in misdirected control strategies while PM_{2.5}, and hopefully also other PM metrics are measured throughout the country. A national strategy to better characterize PM air quality would also provide the groundwork for development of a cost-effective PM control strategy. And, most importantly, there is an urgent need to initiate multiple long-term prospective epidemiologic studies to assess if there is currently a PM problem and, if so, what specific size or chemical fractions are responsible. There is an urgent need for research to establish a mechanism-based causal linkage between PM fractions to be regulated and human disease.

To address research needs such as I have outlined in general terms will require expenditures on the order of \$50 million per year for 5 years compared to the less than \$20 million EPA is expending on PM research in 1997. The alternative to making the research investments and acquiring information for a science-based standard is to proceed blindly with development of standards that will have a multibillion dollar impact and may or may not impact positively on human health. I urge Congress to provide EPA guidance for immediately initiating the expanded research program needed to establish science-based NAAQS for PM.

REFERENCE

- Thurston, G.D., Ito, K., Kinney, P.L., and Lippmann, M. (1992). A multi-year study of air pollution and respiratory hospital admissions in three New York State metropolitan areas: results for 1988 and 1989 summers. *J. Exposure Anal. Environ. Epidemiol.* 2:429–450.

TABLE 1: ESTIMATED HOSPITAL ADMISSIONS FOR ASTHMATICS IN THE NEW YORK CITY AREA FOR VARIOUS OZONE CONTROL SCENARIOS

Row	1H1EX*	1H1EX	8H1EX	8H1EX	8H1EX	8H1EX	8H5EX	8H5EX	AS IS
1	0.12	0.10	0.10	0.10	0.09	0.08	0.07	0.09	≅385d
2	Excess Admissions ^a	210	130	240	180	110	60	180	+83%
	% Δ from present standard	0%	-38%	+14%	-14%	-48%	-71%	-14%	-42%
3	Excess + background ^b	890	810	920	860	790	740	860	1065 ^e
	% Δ from present standard	0%	-9%	+3%	-3%	-11%	-17%	-3%	+20%
5	All Asthma Admissions ^c	28,295	28,215	28,325	28,265	28,195	28,145	28,265	28,205
6	% Δ from present standard	0%	-0.3%	+0.1%	-0.1%	-0.4%	-0.5%	-0.1%	-0.3%
									+0.6%

*1H1EX - 1 hour averaging time, 1 exceedance

a - excess asthma admissions attributed to ozone levels exceeding a background concentrations of 0.04 ppm: from Table VI-2, page 155 in the August 1995 OAQPS Draft Staff Paper

b - asthma admissions included in (a) plus those due to background ozone concentrations; admissions due to background = 1065^e - 385^d = 680

c - asthma admissions due to all causes = 28,470^f - 385^d + Excess Admissions from row 1

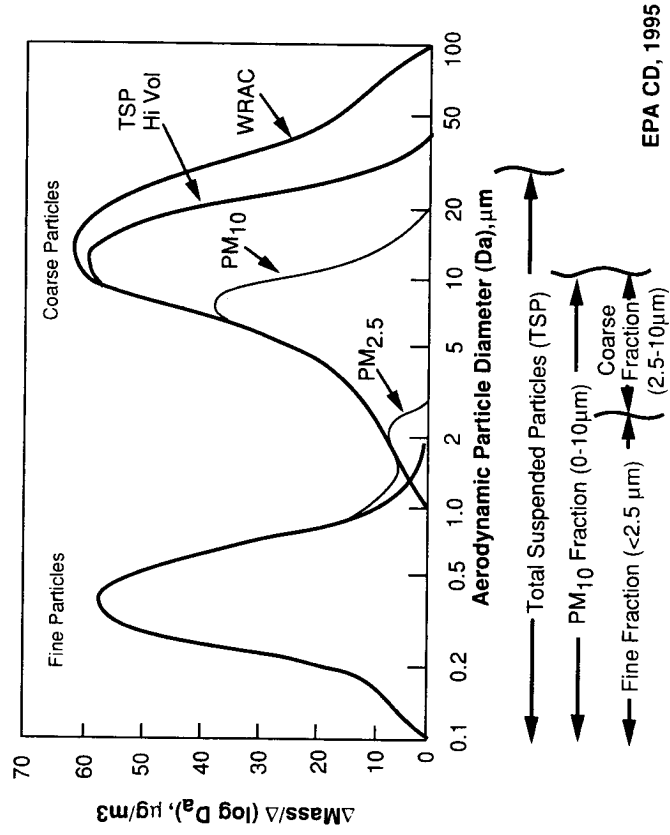
d - estimated from Figure V-15, page 125 in the August 1995 OAQPS Draft Staff Paper

e - from page 127, line 13 in the August 1995 OAQPS Draft Staff Paper

f - total admissions from asthma = total asthmatics (365,000) - from page 126, line 24) x hospitalization rate (78/1000 asthmatics - from page 126, line 29)

Adapted by the Clean Air Scientific Advisory Committee Ozone Panel from the EPA Ozone Staff Paper. The notations in the footnote above refer to the August 1995 OAQPS Draft Ozone Staff Paper

**SAMPLING FRACTIONS FOR AN IDEALIZED
AMBIENT PARTICULATE MASS DISTRIBUTION**



EPA CD, 1995

BIOGRAPHY

ROGER O. McCLELLAN, D.V.M. serves as President of the Chemical Industry Institute of Toxicology, a position held since September 1988. The CIIT is supported by dues payments from some 40 leading industrial firms and has a mission of creating an improved knowledge base for understanding and assessing the adverse effects of exposure to chemicals. Prior to his appointment as President of CIIT, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President and Chief Executive Officer of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. He began his career with Lovelace in 1966, serving as Director, Fission Product Inhalation Program (1966-1973), and later as Vice President and Director, Inhalation Toxicology Research Institute, Lovelace Foundation for Medical Education and Research (1973-1976). During his 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the toxic effects of airborne materials. Prior to joining the Lovelace organization, he was a scientist with the Division of Biology and Medicine, U.S. Atomic Energy Commission, Washington, DC (1965-1966), and Hanford Laboratories, General Electric Company, Richland, WA (1959-1964). He received his Doctor of Veterinary Medicine degree from Washington State University in 1960.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He is past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; a former Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council Committee on Toxicology, Committee on Risk Assessment for Hazardous Air Pollutants, and Committee on Health Risks of Exposure to Radon. He also serves as Adjunct Professor at Duke University, University of North Carolina - Chapel Hill, North Carolina State University, University of New Mexico, and Washington State University. He is active in the affairs of a number of professional organizations, including past service as President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including service as Editor of CRC Critical Reviews in Toxicology. He is a diplomate of the American Board of Toxicology and the American Board of Veterinary Toxicology.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis. He has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment and air pollution, and in the management of multidisciplinary research organizations. He is a strong advocate of risk-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials. Most recently, he served as a member of the EPA Clean Air Scientific Advisory Committee Review Panel for criteria documents and staff papers on ozone and particulate material.

RESPONSE OF DR. MCCLELLAN TO AN ADDITIONAL QUESTION FROM SENATOR HUTCHINSON

Question. The 1990 Clean Air Act Amendments required the EPA to have an independent assessment, which was conducted by the National Research Council. I have the report here. The committee on Tropospheric Ozone Formation and Measurement was established by the NRC to evaluate scientific information relevant to precursors and tropospheric formation of ozone and to recommend strategies and priorities for addressing the critical gaps in scientific information necessary to help address the problem of high ozone concentrations in the lower atmosphere. One of the findings in the study suggests that in many urban cores and their environs, even if anthropogenic (man made) VOC emissions are totally eliminated, a high background concentration of reactive biogenic VOCs will remain.

Further, the Southern Oxidants Study, conducted at North Carolina State University, states that "the complete elimination of anthropogenic VOC emissions will decrease peak ozone concentrations in Atlanta, but still leave parts of the metropolitan area above the present ozone standard under some meteorological conditions." This statement refers to the current standards, not even the more stringent proposed standards.

With this said, is it possible that even if we eliminate all man-made ozone, that other areas in the country could still be out of attainment for ozone?

Response. Yes, if a stringent ozone standard of less than 90 part per billion with an 8 hour averaging time is promulgated it is quite likely that some areas of the country, such as the south eastern U.S. with high background concentrations of reactive biogenic VOCs, will be out of attainment. The lower the 8 hour standard is set the higher the probability that areas will be in non-attainment and the larger the geographic area impacted.

RESPONSE OF DR. MCCLELLAN TO AN ADDITIONAL QUESTION FROM SENATOR LIEBERMAN

Question. In your statement, you express reservations as to the extent to which ozone exposures are a significant contributor to the asthma problem. But don't you agree that ozone exacerbates the asthma problem even if we don't know that ozone causes it?

Response. Yes, ozone is one of many factors that can trigger asthmatic responses in asthmatic individuals. However, there is no evidence that ozone is the underlying factor causing the individual to be an asthmatic.

Recently Published Epidemiological Studies Examining Mortality and Ambient Particulate Matter Which Appeared in EPA PM Criteria Document Table 12-2

Author (year)	PM Measure ^b	Confounders ^c		Weather	PM Association ^d
		Copollutants	Weather		
Schwartz et al (1996)	PM10/PM2.5	No	Yes	Yes	Yes
Ito and Thurston (1996)	PM10	Yes	Yes	Yes	Yes
Lyon et al (1995)	PM10	No	No	No	No
Styer et al (1995) - Chicago and Salt Lake	PM10	No	Yes	Yes	Yes
Saldiva et al (1994)	PM10	Yes	Yes	Yes	No
Ostro et al (1996)	PM10	Yes	Yes	Yes	Yes
Ito et al (1995)	PM10	No	No	No	Yes
Kinney et al (1995)	PM10	Yes	Yes	Yes	Yes
Ozkaynak et al (1994)	PM10	Yes	No	No	No
Schwartz (1993)	PM10	No	Yes	Yes	Yes
Dockery et al (1992)	PM10/PM2.5	Yes	Yes	Yes	Yes
Pope and Kalkstein (1996)	PM10	No	Yes	Yes	Yes
Pope et al (1992)	PM10	No	Yes	Yes	Yes
Xu et al (1994)	TSP	Yes	Yes	Yes	No
Derrinmic et al (1989)	TSP	Yes	Yes	Yes	No
Schwartz (1994)	TSP	No	Yes	Yes	Yes
Moolgavkar et al (1995)	TSP	Yes	Yes	Yes	No
Schwartz and Dockery (1992)	TSP	Yes	Yes	Yes	Yes
Cifuentes and Lave (1996)	TSP	Yes	Yes	Yes	Yes

^a "No" means the author did not take confounders (other possible causes) into account. "Yes" means the author did.
^b How PM was measured in the study. TSP refers to particles as large as 45µ. PM-10 refers to 10µ particles and PM-2.5 to 2.5µ particles.
^c BS, COH, KM and SP basically measure particles of various sizes.
^d "Yes" means the author found a statistical association between PM only and adverse health effects. "No" includes those studies that had no statistically significant association and those such as Samet et al (1996) which concluded that "a single pollutant of the TSP, SO2, NO2 and CO cannot be readily identified as the best predictor of mortality."

Recently Published Epidemiological Studies (continued)

Author (year)	PM Measure	Confounders/ Copolutants	Weather	PM Association
Samet et al (1996)	TSP	Yes	Yes	No
Samet et al (1996)	TSP	Yes	Yes	Yes
Samet et al (1995)	TSP	Yes	Yes	Yes
Li and Roth (1995)	TSP	Yes	Yes	No
Wynga and Lipfert (1995)	TSP	Yes	Yes	Yes
Moolgavkar et al (1995)	TSP	Yes	Yes	No
Schwartz and Dockery (1992)	TSP	No	Yes	Yes
Schwartz (1991)	TSP	Yes	Yes	Yes
Touloumi et al (1994)	BS	Yes	Yes	No
Katsouyanni et al (1993)	BS	Yes	Yes	No
Katsouyanni et al (1990)	BS	Yes	Yes	Yes
Spix et al (1993)	SP	Yes	Yes	Yes
Thurston et al (1989)	BS	Yes	Yes	Yes
Fairley (1990)	COH	No	Yes	Yes
Kimney and Ozkaynak (1991)	KM	Yes	Yes	No
Shunway et al (1988)	KM	Yes	Yes	Yes

"No" means the author did not take confounders (other possible causes) into account. "Yes" means the author did.

How PM was measured in the study. TSP refers to particles as large as 45µ. PM-10 refers to 10µ particles and PM-2.5 to 2.5µ particles. BS, COH, KM and SP basically measure particles of various sizes.

"Yes" means the author found a statistical association between PM only and adverse health effects. "No" includes those studies that had no statistically significant association and those such as Samet et al (1996) which concluded that "a single pollutant of the group TSP, SO₂, NO₂, and CO cannot be readily identified as the best predictor of mortality."

PREPARED STATEMENT OF DR. ANNE E. SMITH, VICE PRESIDENT,
DECISION FOCUS INCORPORATED

My name is Dr. Anne E. Smith. I am a Vice President and Principal of Decision Focus Incorporated, a consulting firm with offices in Mountain View, CA, Washington, DC, and London, UK. I have 20 years of experience in environmental risk assessment and risk management, founded on a Ph.D. in economics from Stanford University. I started my professional career in the U.S. EPA's Office of Policy, Planning and Evaluation in 1977, where I was involved in air quality issues such as airborne arsenic regulations and EPA's air cancer policy. Over the 18 years since, I have contributed to a wide range of major environmental science/policy assessments for the U.S. Environmental Protection Agency, the National Acid Precipitation Assessment Program, the Grand Canyon Visibility Transport Commission, the Electric Power Research Institute, the Gas Research Institute, and many others.

In 1980, I was one of the experts selected by the U.S. Environmental Protection Agency's Office of Air Quality Planning and Standards to develop methods for assessing risks from criteria air pollutants, with a demonstration assessing risks from ambient carbon monoxide. I also served the United Nations Economic Commission for Europe in preparing a plan for analyzing acid rain control strategies. In the late 1980's, I worked closely with the Director of the U.S. National Acid Precipitation Assessment Program, advising on methods for integrating the scientific research into a comprehensive assessment. Recently, I developed the system used by the Grand Canyon Visibility Transport Commission to assess alternative policies for managing the particle precursors that contribute to impaired visibility in the Southwest. I also performed the economic analyses of the Commission's recommended visibility management alternatives. In addition to my consulting engagements, I have served on a number of expert panels on risk assessment, including two committees of the National Academy of Sciences, a Keystone Foundation dialog, and two committees of the United Nations Environment Programme.

I am honored to have this opportunity to speak with you today about the science supporting the proposed new standards for fine particulate matter, PM_{2.5}. My statement reflects my personal opinions, and not those of my company or any other group.

In previous statements on this issue, I have likened the current situation for PM to the classic "Shell Game"—the one where you try to guess which of several walnut shells is covering a pea. The proposed fine particle standard would force the expenditure of a great deal of money to reduce PM from a variety of sources, yet it is far from clear that the proposed standard would successfully target the true culprit that is causing adverse health impacts. We could turn over many empty shells, at great expense, but with little benefit to public health. I will explain why.

WHAT IS THE EVIDENCE OF A PM-RELATED HEALTH EFFECT?

There are a number of statistical, or "epidemiology", studies that seem to indicate that as ambient PM goes up and down, so too do the levels of health effects. However, when we observe two types of data going up and down together, we should not necessarily conclude that there is a causal relationship between the two phenomena. For example, if we were to observe such an association between heat stress mortality and ice cream cone sales, few people would suggest that one is caused by the other. The error in this example is so obvious to us because we all have a good understanding of the biological processes that result in heat stress. So, when we have statistical evidence of the sort that seems to suggest that ambient PM and mortality go up and down together, we also want to have scientific data about biological processes associated with PM to help us explain why we should believe this is a causal relationship and not just a statistical association.

WHAT DOES THE SCIENCE TELL US ABOUT A BIOLOGICAL EXPLANATION?

If you review EPA's Criteria Document for PM, you will find that EPA concludes that "no credible supporting toxicologic data are yet available."¹ That is, when very high levels of various types of PM constituents have been inhaled or otherwise placed in the lungs of humans or animals, no one has observed a consistent response of the tissues that could be clearly linked to the health effects observed in the statistical studies. This inability to elicit significant and consistent biological responses to high levels of PM exposure is troubling, since you might expect adverse changes to be readily observable in laboratory experiments if the health effects were as large as the statistics seem to suggest. Toxicological evidence suggesting adverse

¹USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13-31.

health effects is present for other criteria pollutants (e.g., ozone, carbon monoxide, sulfur dioxide, nitrogen oxides, etc.).

The inconsistency between the statistics and the toxicology findings give us a strong motivation to try to develop a line of physiological or medical reasoning to explain whether or not these statistical relationships are biologically plausible. Attempts to provide such reasoning have been at best speculative. In the peer-reviewed Criteria Document, EPA suggests that such reasoning is not compelling: "There is . . . a paucity of information . . . that argues for the biologic plausibility of the epidemiologic results."² Those attempts that have been made to construct an argument for biological plausibility for mortality (which is what is driving the large benefits estimates for the proposed standard) have suggested that the susceptible person is very much on the edge of life: for example, "a triggering of a lethal failing of a critical function, such as . . . lung fluid balance . . . in [people] already approaching the limits of tolerance due to preexisting conditions."³ Under such circumstances, any of a number of air contaminants could have the same effect on the person. I don't find these plausibility arguments a compelling case for PM alone, because (1) these arguments could be used to explain the effects of many other air pollutants or weather patterns, while also (2) there are some very good reasons why the statistical results could be picking up the effect of one of these other possible contributors, as I will now explain.

WHAT ARE THE STATISTICAL REASONS TO DOUBT THAT PM IS TRULY CAUSING THE OBSERVED MORTALITY?

We are faced with a situation where statistical results have not been corroborated by the rest of the sciences. As every first-year statistics student is taught, it is very easy to make big mistakes with statistics in this situation. This is why many of the researchers, whose findings EPA is using, describe PM as a possible "surrogate for" or "correlate of" a yet-to-be-known specific culprit.⁴

In statistical studies cited in EPA's Criteria Document, researchers looked for patterns of association between PM and mortality. The difficulty is that the data to do this contain many types of random variations, and the relationships we are looking for are probably complex. There are many types of statistical errors that one can commit when analyzing data that contain random variations, and there are many ways of trying to avoid or minimize statistical errors. The Criteria Document describes these statistical errors and the potential for misinterpreting statistical results.⁵ Due to these potential errors, the Criteria Document states that "confident assignment of . . . variations in health endpoints to specific air pollutants may still require additional study"⁶ and also concludes that "much caution is warranted with regard to derivation or extrapolation of quantitative estimates of increased risks . . . based on available epidemiology information."⁷

The question for me has been, How much caution is warranted? Recently, I started to explore the likelihood that these errors might be large enough to affect the overall qualitative picture of PM risks that can emerge from statistical studies. As a result of some numerical experiments of my own, I believe that we need to really look much more closely at the potential errors in the statistical results than EPA has done to date. This is because the PM studies exhibit two distinct types of data problems at the same time. It may seem arcane to worry about combinations of problems, but the common statistical methods for detecting these errors individually don't work when both of the following common data problems are present in the same data set:

- (1) Several different pollutants in the data tend to rise and fall with similar patterns (i.e., levels of various pollutants are "correlated"); and
- (2) There is more difficulty in getting good estimates of people's actual exposures for some of the pollutants than for others (i.e., there are differences in "measurement errors").

These are very common problems for ambient pollution data. They both occur to a certain degree in all of the PM studies; they occur together. My numerical experi-

² USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–31.

³ See USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–51 to 13–57.

⁴ See for example, Health Effects Institute, *Particulate Air Pollution and Daily Mortality: Replication and Validation of Selected Studies*, August 1995, page v.; and abstract of Pope et al., "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults," *Am. J. Respir. Crit. Care Med.*, Vol. 151, pp. 669–674, 1995.

⁵ See USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–51 to 13–57.

⁶ USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–93 to 13–93.

⁷ USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–32.

ments with these two effects (correlations and differential measurement errors) have suggested to me that the epidemiological conclusions on PM may not only be subject to quantitative inaccuracy, but actually may be at odds with the truth in a qualitative sense. In my numerical experiments, a pollutant that was constructed to have a perfect relationship with the mortality data repeatedly appeared to have no statistically significant relationship. A pollutant that was constructed to have no effect on mortality repeatedly appeared to have a strong and statistically significant effect.⁸

It is not surprising that I could generate such results, since the potential for such errors has been proven theoretically.⁹ However, I was surprised at how large and consistent the error in the statistical conclusions was when I used realistic values for degree of correlation and measurement error. If these typical data conditions really can be this effective in getting us to draw incorrect conclusions, then it means that we could be finding consistent statistical evidence implicating fine PM across numerous studies in many locations and over different periods of time, even if fine PM were having little or no causal effect on mortality at all. One or more other factors may be the real cause.

If this potential statistical error cannot be addressed satisfactorily, then reduction of uncertainty about the causative role of PM₁₀ or PM_{2.5} should depend very heavily on obtaining corroborating scientific evidence of a biological mechanism.

BUT WHAT IF WE DECIDE TO BELIEVE THERE IS A FINE PARTICLE EFFECT ANYWAY?

I have given you my reasons for skepticism about the statistical evidence. But everyone has to draw their own conclusions, and other people may be prepared to believe that there really is a significant fine particle effect. If we were to have confidence there is a fine particle effect, then would we have enough information to set standards that are protective of the public health? I think not. The Shell Game still applies, and at this point, the existing statistical studies do not even pretend to be able to help.

Why? Look at what PM_{2.5} consists of. Unlike any other criteria pollutant, it is made up of many components, and each component is like another shell that may or may not contain the pea. Particles come from many types of sources, and for each source, the particles consist of very different chemicals and particle sizes. These differences may be highly significant for health. Not one of the available statistical studies on PM has attempted to unravel the roles of all the key types of PM constituents, simply because there are no statistically usable data about how these constituents vary in different places and at different points in time. As a result, consider the effect on these policy-relevant questions:

- Are some specific PM constituents creating a toxic effect, while other parts of the PM mix are non-potent? . . . No one yet knows.
- Have we deduced the likely importance of the various constituents from biological data? . . . Not yet.
- If we require reductions of fine particles generically, can we be confident that the true culprit or culprits will end up being controlled? . . . No.

The true culprit is not known, and better statistical analysis will not resolve this uncertainty; only better exposure data will. Better laboratory and clinical-level information on health effects will also help. Until we have data that can start to reveal the roles of the constituents in the PM mix, and the role of PM versus other pollutants, we cannot expect to have better answers to these important policy questions. Thus, use of current scientific information to set public policy amounts to playing a classic "Shell Game," even if you believe fine particles cause adverse health effects.

Let me try to illustrate the dilemma by reviewing some of the hypotheses described in the Criteria Document:

- Some toxicological evidence points not to the fine particles, but the ultrafine particles (e.g., less than 0.1 μm in diameter).¹⁰ This would suggest that regulations should target combustion sources that are very close to people, such as automobiles.
- Another hypothesis relates to how acid the particles are.¹¹ Acid particles mostly come from sources of SO_x and NO_x, such as power plants.

⁸A briefing on these results could be provided to the Subcommittee.

⁹See, for example, Lipfert, F.W. and R.E. Wyzga, "Uncertainties in Identifying 'Responsible' Pollutants in Observational Epidemiology Studies," *Inhalation Toxicology*, 1995, Vol. 7, pp. 671-89.

¹⁰USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13-76 to 13-78.

¹¹USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13-72 to 13-76.

- Yet another hypothesis points to long-term accumulation of particles in the lungs.¹² This would suggest controls on those particles that are not soluble, such as road dusts, and soot from diesel combustion.

The list of hypotheses and potential culprits goes on. It seems unlikely that all of the hypothesized physiological effects will turn out to be equally important. Until we know which of the hypotheses to believe, we run the risk of controlling particles that don't significantly harm the public health. And, we run the risk of not controlling particles that do create a public health hazard. I do not have confidence that we will end up controlling the right constituent if we set a generic fine particle standard as proposed.

HOW HAS EPA COMMUNICATED ABOUT THESE UNCERTAINTIES IN ITS RISK AND BENEFITS ASSESSMENTS?

EPA's peer-reviewed Criteria Document for PM describes the pitfalls that need to be considered in the use of the statistical findings,¹³ and issues warnings about using the statistical results as an actual dose-response:

“There remains much uncertainty . . . regarding the shapes of PM exposure-response relationships, the magnitudes and variabilities of risk estimates for PM, the ability to attribute observed health effects to specific PM constituents . . . and the nature and magnitude of the overall public health risk imposed by ambient PM exposure.”¹⁴

Despite these warnings in the peer-reviewed Criteria Document, EPA's Staff Paper and its Regulatory Impact Analysis have all used the statistically derived estimates as if they give us a reasonable approximation of a causal relationship, with no uncertainty other than the error bars reported in the single study used for each health endpoint. As I have explained above, those statistically derived error bars may themselves be unreliable. And, in the case of the benefits ranges in the Regulatory Impact Analysis, even the statistical error bars have been dropped; uncertainty analysis has devolved to two point estimates from two individual studies,¹⁵ and EPA seems to imply that this is the major source of uncertainty in these benefits estimates:

“The uncertainty associated with the benefits estimates are substantial. In particular, benefit estimates vary greatly depending [whether the long-term or short-term mortality study is used to estimate mortality benefits].” (emphasis added).¹⁶

Thus, EPA has made several very important presumptions in the risk analyses and benefits estimates that it is using to support its proposed PM_{2.5} standards:

- EPA's risk analysis presumes that if the statistical indicator or surrogate is controlled, that the actual culprit also will be controlled.

Until we are confident that the statistical association is evidence of causation, this is like the ancient Greek practice of killing the messenger who delivers bad news. For example, ambient levels of PM might simply be correlated with another factor that is the true culprit, such as carbon monoxide or weather. Reducing PM would not produce any health benefits—at the moment it is still only a kind of “statistical messenger”, telling us that some kind of health effect exists in our environment.

- Even if PM_{2.5} is a problem, EPA's risk analysis also presumes that any action taken to reduce PM_{2.5} will certainly control the specific culprit.

For example, if organic carbon particles are the culprit, controls on SO_x and soot are still assumed to provide health benefits. This is like assuming that we can win the Shell Game no matter what shell we look under.

There are many other types of uncertainties in the risk analysis that EPA's staff also have not incorporated, and which I have described in earlier formal written

¹²USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–23.

¹³USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–51 to 13–57.

¹⁴USEPA, *Air Quality Criteria for Particulate Matter*, April 1996, p. 13–30.

¹⁵The estimate of \$58 billion is based on “short-term mortality”, using the 1996 Schwartz et al. “Six Cities” study. The estimate of \$119 billion is based on “long-term mortality”, using the 1995 Pope et al. Study. No uncertainty of any sort is incorporated into any benefits estimates in the *Regulatory Impact Analysis* other than whether short-term or long-term mortality is the relevant health endpoint for making benefits estimates.

¹⁶USEPA, Office of Air Quality Planning and Standards, *Regulatory Impact Analysis for Proposed Particulate Matter National Ambient Air Quality Standard*, November 4, 1996, p. 10–4.

comments to EPA.¹⁷ Overall, EPA's estimates of the benefits of the proposed PM_{2.5} standards do not reflect the real uncertainties that statisticians openly acknowledge in their publications, and which EPA describes in its own Criteria Document. The \$58 to \$119 billion per year of benefits that EPA estimates we will obtain from the proposed PM_{2.5} standard¹⁸ is actually like a lottery that we might win—if all of these presumptions are correct. At the same time, there is a substantial probability that the benefits could be very small, even zero.

DOES THE NATION WANT TO PLAY THIS SHELL GAME?

This is a valid policy question. Given the large cost of the proposed regulation, it deserves an open public debate tempered with a willingness to acknowledge the true state of scientific understanding. Since the costs of any additional regulation would be undertaken with a degree of uncertainty that has the quality of a Shell Game, it is essential to good public policy that this decision be informed by estimates of risks and benefits that properly reflect the true extent of uncertainty that we are facing.

The state of science leaves a reasonable chance that the proposed PM_{2.5} standard would not generate any significant benefits at all. In such a situation, it is also reasonable to consider whether there are more effective ways of protecting the public health. I have seen no serious discussion from EPA of the merits of regulatory options other than a generic PM_{2.5} standard. The proposed PM_{2.5} standard has not been designed to try to manage the uncertainties I have described. It does not account for or suggest the relevance of trying to maximize the chances that the most likely culprits will be controlled. Why should anyone expect this standard to accidentally hit the right target?

We should try to aim more carefully, with a more thorough consideration of the uncertainties, and of alternatives that can improve our likelihood of achieving the desired public health benefits. I am not suggesting years of delay . . . I am suggesting better risk management through a more complete assessment of the uncertainties, and a more complete assessment of alternative regulatory approaches.

¹⁷Smith, Anne E., "Comments on Risk Analysis in EPA's Draft *Staff Paper* for a Particulate Matter National Ambient Air Quality Standard", submitted with the official comments from the Utility Air Regulatory Group on the Draft PM *Staff Paper*, June 6, 1996. (Note: Although this reference provides comments on the draft version of the *Staff Paper*, the concerns that it raises remain relevant to the final *Staff Paper*.)

¹⁸USEPA, *Regulatory Impact Analysis for Proposed PM_{2.5} Standard*, November 1996, table 9.8.



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March 11, 1997

Members of the Senate Committee on Environment and Public Works
Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety
United States Senate
Washington, DC 20510

Dear Senator:

Enclosed you will find a copy of my response to written questions from Senators James Inhofe and Tim Hutchinson. This supplements my testimony of February 5, 1997 to the Subcommittee and was formally submitted to the Committee office on February 25, 1997.

As I promise in the written responses, I am sending Subcommittee members a copy of the paper on these issues that I have just finalized. It is entitled, "How Statistics Can Mislead PM Policy: A Case of Smoke and Mirrors?" This paper is being submitted to the United States Environmental Protection Agency as a part of the Utility Air Regulatory Group's written comments on the proposed PM regulation.

Recently, *Inside EPA's Risk Policy Report* published my article, "The Real Particulate Matter Culprit: EPA's Flawed Assumptions," which articulates additional thoughts on the PM regulatory issue. Again thank you for the opportunity to present this important information to you. If I can be of further assistance, please contact me.

Sincerely,

A handwritten signature in cursive script that reads "Anne E. Smith".

Anne E. Smith, Ph. D.
Vice President

enclosures

DR. ANNE SMITH'S RESPONSE TO QUESTION FROM SENATOR TIM HUTCHINSON

Question 1. Could you elaborate on the issue of a lack of monitoring data in our largest cities, what is needed to alleviate this need, including how long would be needed to conduct a thorough study, and once that data is gathered, what is needed to analyze it?

For a situation of this complexity, epidemiologic evidence alone is unlikely to ever be sufficient to prove causality. Future research plans need to focus most heavily on toxicological studies and clinical and laboratory studies. More and better monitoring data will not address that more critical data need. However, if we also want to improve the uncertainties in the epidemiologic risk estimates, there are several critical exposure data weaknesses that need to be addressed:

- PM_{2.5} must be directly monitored, not estimated from PM₁₀ data as is the case for many of the epidemiologic studies that purport to have considered PM_{2.5}. As you point out, we have essentially no current PM_{2.5} monitoring network that provides an on-going stream of directly measured ambient PM_{2.5} levels. The only coordinated PM_{2.5} monitoring at present is the IMPROVE network, which is rural and therefore not relevant to understanding risks to the majority of the U.S. population. Even though about 43 of the IMPROVE sites do monitor rural PM_{2.5}, these data are not appropriate to use, and have not been used, in the epidemiologic studies. The PM_{2.5} data for 50 cities that were used in the 1995 American Cancer Society study (which is the basis for EPA's high estimates of benefits from "long-term mortality" risk) are over 15 years old, and do not represent a current monitoring network. The PM_{2.5} data used in the 1996 "Six Cities" study by Schwartz, Dockery and Neas (which is the basis for EPA's estimates of benefits from "short-term mortality" risk) is about 10 years old, exists for only six cities, and is proprietary: no one other than Harvard researchers can make use of these monitored data. As a result, most other studies have had to resort to using PM_{2.5} data that is approximated from PM₁₀ or TSP data.
- Whether we are monitoring PM_{2.5} or PM₁₀, we need a greater density of samplers for epidemiologic studies. The current PM₁₀ network was designed to determine compliance, not to provide data of the quality necessary for good epidemiology. As a result, all the existing statistical studies, whether for PM_{2.5} or PM₁₀, use a single monitor to approximate actual individual exposures over dozens of miles. For example, in the "Six Cities" study, a single monitor in Harriman, TN was used to estimate PM_{2.5} exposures of people over 50 miles away in Knoxville, TN. Until the PM monitors are closer to the people whose health is being monitored, there will be large measurement error in these studies, making them very weak evidence of health impact.
- Personal exposures must be monitored. We need to actually track the exposures of individuals and compare their actual PM exposures to those that would be estimated using local ambient monitor data. This is necessary to understand how much confidence we can give to ambient data as a sign of population exposures, and to determine how dense the PM monitoring network needs to be to improve the quality of epidemiologic studies.

- Individual constituents in the PM mix need to be monitored too. Until we have information about how the many constituents of $PM_{2.5}$ are changing over time and over space, we will not have any ability to study one of the most significant information gaps: whether the culprit is all types of PM, or some subset of PM, or some non-PM pollutants. Constituent-level monitoring would not be required under a $PM_{2.5}$ standard. Besides, the proposed method for measuring $PM_{2.5}$ (EPA's "Reference Method") has substantial technical inadequacies that will lead to very inaccurate estimates of individual constituents, and thus also of the total $PM_{2.5}$ concentrations. Thus, this important data gap may not be possible to close even with a substantial investment in a $PM_{2.5}$ monitoring network as proposed by EPA.
- We need simultaneous measurements of other potential culprit pollutants. Another very critical problem with the epidemiologic evidence is its failure to address other pollutants that may also be causing some or all of the observed health effects. Better $PM_{2.5}$ data is not enough: we need better data on all the potential culprit pollutants for the same populations.

Several researchers have suggested that about 5 years will be needed to collect the additional data to improve our data gaps. This would be a minimum amount of time to set up the network, collect sufficient data, and perform preliminary analyses. What is important to emphasize, however, is that more is needed than 5 years of better ambient $PM_{2.5}$ monitoring data. We need the personal monitoring studies to help us understand the degree of error that we make when estimating a population's pollutant exposures from ambient monitor data, we need constituent-level data to try to determine whether observed effects are associated with PM from specific types of sources, and we need data for non-PM, gaseous pollutants, to allow the studies to properly seek out potential culprits from the full set of possible candidates. If we do not somehow start understanding and accounting for the differences in measurement errors among all the possible culprits, no amount of additional data on $PM_{2.5}$ will result in better epidemiology studies.

DR. ANNE SMITH'S RESPONSES TO QUESTIONS FROM SENATOR JAMES INHOFE

Question 1. You mentioned that you have yourself developed estimates of measurement error problems that give you concern. Could you describe the nature of those experiments and results.

It is well known that measurement error leads to biased estimates of the relative risk, and can make it infeasible to detect a threshold or other strong non-linearity in a relationship between ambient air pollution and health effects. It is also known that if measurement error is larger for one pollutant than for another, then the statistical regression techniques of epidemiology might incorrectly make one pollutant seem more potent than the other. Like many other people facing these facts, I wasn't sure how much importance I should ascribe to these statistical complications. Is this a relatively minor source of error? Or could these biases be so large that they might be able to undermine arguments that the epidemiology studies are showing a "real" relationship between PM and health? When I am faced with questions like this, I like to construct hypothetical numerical examples to test how strong the effect can be under a range of possible data conditions. Then I can determine for myself just how much emphasis I should give to an issue. In other words, I let the numerical experiments help me sort out issues that really might distort the bottom line conclusion from issues that are interesting theoretical points, but aren't likely to really alter the bottom line conclusion. I have done a number of these types of numerical experiments for issues that have been raised in the PM health debate; the measurement error issue has stood out as one of the most important problem areas that I have explored. I will try to describe what I have discovered and how in the following paragraphs.

Briefly, I found that quite realistic levels of inaccuracy (as defined below) in estimates of actual exposures to two correlated pollutants can be sufficient to create so much bias in regression estimates of their respective health impacts that epidemiologic techniques could consistently and strongly implicate a completely innocent pollutant and not find any strong or statistically significant relationship between health and the actual culprit pollutant. I also found that if these "measurement errors" are sufficient to cause such false conclusions under one set of data, then this erroneous conclusion would occur over and over, under many different sets of data that contain the same degree of measurement error. This is not a randomly occurring bias that may happen one out of 100 times – it is a structural bias. A 99% confidence level in statistics does not account for this kind of structural error, and is meaningless as evidence against the presence of this kind of error.

I am in the process of preparing a detailed written explanation of the actual numerical calculations, but I will briefly summarize them here. The longer description will be submitted with formal comments to EPA on the proposed PM_{2.5} standard at the time of the March 12 deadline. It is being written in the form of a non-technical explanation of the implications of measurement error and confounding, hopefully to provide readers with an intuitive rather than theoretical understanding of how measurement errors can end up generating such incorrect statistical conclusions. I will forward the full description to all the members of the subcommittee when it is finalized. In the meantime, I will summarize what was done numerically to cause me to come to the conclusions I stated above. A colleague at Decision Focus Incorporated, Dr. Nathan Chan, assisted me in conducting these numerical experiments.

First, we created daily data for a hypothetical "culprit" pollutant with a well-defined relationship to health: as the pollutant increased, so would mortality. The hypothetical relationship was that for every extra unit of that pollutant on a given day, there were a specific number of extra deaths that day. There were no errors or noise in the data we created: this would be a very easy relationship to detect statistically. We also created daily data for a second "innocent" pollutant: no matter what the level of the innocent pollutant, there were no increased deaths. Using the daily levels of the culprit pollutant, we generated the number of daily excess deaths according to the relationship mentioned above. Thus, we created a data set that included the daily number of excess deaths, and associated daily pollutant exposures for two different pollutants. We applied standard epidemiological techniques of regression analysis to see what relationship the statistics would find based on these data.

As one would hope, when there was no measurement error and no correlation between the two pollutants, the statistics picked out the first pollutant as the culprit, and identified the numerical relationship with perfect accuracy.

Next, we added some correlation between the two hypothetical pollutants, so that as the culprit pollutant went up and down, there was a strong likelihood that the innocent pollutant would go up and down too. This is the condition commonly called "confounding". We applied a "positive correlation", meaning that the pollutants generally tend to move in the same direction as each other. This simulates the real world, where pollutants like NO_x, SO_x, carbon monoxide, and PM_{2.5} all tend to be higher on some days, and all tend to be lower on other types of days. Even with this correlation, the epidemiologic methods still easily discerned which of the two pollutants was the true culprit because there is no randomness or other sources of variability in the mortality relationship that we have constructed.

However, we then started to add a single form of randomness to the data: measurement error. That is, for each day in the data set, we took the actual pollutant exposures for both pollutants, and approximated them by adding on a randomly determined amount of error (we used a computerized random number generator to create these measurement errors). We then used the approximated exposure data in the regressions. This is a very real form of error in the actual data of all the existing studies on PM, because they are all using data from one or a few monitored locations to approximate actual exposures of large groups of people for dozens of miles around. We found that even small amounts of this single type of randomness cause the statistical methods to have trouble determining which pollutant is the culprit. The innocent pollutant starts to show a statistical association with health (erroneously, of course); and this effect is apparent even if we estimate the pollutant exposures with better than 90% accuracy (i.e., the measurement error is within plus or minus 10% of the actual pollutant exposure). This erroneous relationship is statistically significant even when the culprit and the innocent pollutants are both in the regression simultaneously. As measurement errors are increased to about plus or minus 50%, the regression results suggest that both pollutants are equally potent, even though we know that one of them is not potent at all.

In reality, pollutants are measured with different levels of accuracy, and this is where the epidemiology errors become truly serious. This is where the culprit can appear to be a non-significant contributor and the innocent pollutant can appear highly significant, even when both

pollutants are included in the regression. We have seen discussions indicating that measurement error can easily be over 50%, and can easily be much greater for some pollutants than others, due to very large differences in the spatial variations in concentrations. One experimental case we looked at involved a "pretty good" approximation of exposures to the innocent pollutant (about 25% random error applied to the actual exposures), and a "pretty poor" approximation of actual exposures for the culprit pollutant (about a 100% random error applied to the actual exposures). The correlation between the pollutants was 0.56 (on a scale of 0 to 1). When we ran regressions on data with these levels of errors, we found that the culprit never appeared to have a strong relationship, and the innocent pollutant was consistently showing a strong, statistically significant relationship. On average, over multiple different experiments, the estimated relative risk for the innocent pollutant was about 8 times higher than the estimated relative risk for the true culprit. Also, the measure of statistical significance for the innocent pollutant's relative risk (the "t-statistic") was 7 times larger than the significance measure for the culprit. Effectively, the culprit would not be accepted as having a statistically significant relationship at all. This kind of statistical reversal of reality occurred with much more optimistic assumptions about levels of measurement error, where we could measure the innocent pollutant with over 90% accuracy, and we could measure the culprit with over 50% accuracy.

Our experiments indicated that differences in measurement error matter more than the degree of measurement error. Differences in measurement errors among real-world pollutants are realistic: gaseous pollutants such as carbon monoxide and NO_x , and the coarse fraction of PM_{10} tend to drop off rapidly away from their sources. By contrast, $\text{PM}_{2.5}$ and SO_2 tend to have fairly constant levels over broad areas. SO_2 may be somewhere in between the two groups. All these pollutants are positively correlated, however. What if carbon monoxide or NO_x were the true culprit in the real world, and $\text{PM}_{2.5}$ were not causing health effects at all? What if both $\text{PM}_{2.5}$ and the coarse fraction of PM equally contribute to health effects? If, in the real world, any of the gaseous pollutants or any of the coarse fraction are actually causing health effects, these numerical experiments tell us that epidemiologic methods run a substantial risk of falsely indicating that $\text{PM}_{2.5}$ is the only culprit.

Question 2. How do you account for the apparent discrepancies between your findings on measurement error problems and the analysis described by Drs. Schwartz, Dockery and Neas in their 1996 Air & Waste Management Association paper, which seemed to imply very minor potential biases?

My numerical experiments highlighted cases where $PM_{2.5}$ is not the primary or sole health effects culprit, yet epidemiology can falsely identify it as such. The examples on measurement error in the paper by Schwartz, Dockery and Neas do not involve conditions where epidemiology could erroneously suggest that $PM_{2.5}$ is the culprit. Their two examples both presume that $PM_{2.5}$ is the culprit. In other words, we have each analyzed different sets of conditions, which each lead to different types of errors. All of these sets of conditions are equally valid possibilities. However, since the epidemiology studies are finding a strong positive association for $PM_{2.5}$, the important question at this point in time is whether there are realistic conditions not yet analyzed in those studies under which this association might not reflect a causal relationship. My examples have shown that such realistic conditions can exist and they have not yet been studied. Their examples do not disprove this point, or even address it.

To clarify, I have listed in Table A all of the possible combinations of conditions for two pollutants ("pollutant A" and "pollutant B") that are positively correlated with each other. The table describes the statistical problems that would appear in each case. There are four combinations: the case where only one of the pollutants is responsible for the health effects, and the case where both of the pollutants are responsible, for each of which, one pollutant or the other has the larger measurement error. If you replace "A" with " $PM_{2.5}$ ", then Cases 1 and 2 are situations where $PM_{2.5}$ might be an innocent pollutant yet ends up being falsely identified as the culprit. Cases 1 and 2 are the ones that give us the most concern: these are the situations where we would be making a big mistake if we were to regulate $PM_{2.5}$ on the basis of the current epidemiologic evidence. These are the cases that my experiments find to be potentially real. These are not addressed in the Schwartz, Dockery and Neas paper. In fact, their paper suggests that to consider these other cases "would only confuse the paper and analyses" (p. 936, *AWMA*, October 1996). Such cases are confusing; they are also difficult to study given the lack of data on the other pollutants, and they do reduce the statistical "power" of the analysis, but they represent the critical potential mistakes that could come from believing these epidemiologic results.

Table A. Possible Measurement Error Conditions for Two Positively Correlated Pollutants, and Potential Resulting Epidemiologic Errors

	Which pollutant (A or B) is true culprit	Difference in measurement error	Resulting bias in statistical results
1.	A is innocent; B is culprit	A has smaller meas. error	Strong chance A would be falsely accused; Strong chance B would be falsely deemed insignificant.
2.	A is innocent; B is culprit	B has smaller meas. error	Some chance A would be falsely accused; Some chance B would be falsely deemed insignificant.
3.	Both A and B are culprits	A has smaller meas. error	Magnitude of A's role will be overstated; B's role will be understated and B may be falsely deemed insignificant.
4.	Both A and B are culprits	B has smaller meas. error	A's role will be understated and A may be falsely deemed insignificant; Magnitude of B's role will be overstated.

Schwartz, Dockery and Neas have focused on Case 3 in Table A, where $PM_{2.5}$ is a culprit and is measured with relatively small error. For example, they describe a case where temperature and dewpoint information are made so erroneous as to be missing (think of them as "pollutant B"), and $PM_{2.5}$ is given an incremental error on the order of 10%. In Case 3, the worst possible statistical error with regard to $PM_{2.5}$'s role is that it's potency might be overstated, or "biased upwards". Their example shows that for weather vs. $PM_{2.5}$, with errors of the relative magnitude assumed, the upward bias is on the order of 13% for every 10% of error estimating actual $PM_{2.5}$ exposures. This does not disprove that Cases 1 and 2 may also be at work: even without the controls for weather-related conditions, $PM_{2.5}$ could still be reflecting the effects of other pollutants.

The second example on measurement error provided in the Schwartz, Dockery and Neas paper also relates to Case 3 of Table A. They discuss the effects of measurement error on $PM_{2.5}$ and CM (the coarse fraction of PM_{10}), and suggest that such errors could not explain $PM_{2.5}$'s greater statistical significance. (Think of "A" as " $PM_{2.5}$ " and "B" as "CM".) Unfortunately, in this example their logic and analysis are wrong in two ways:

1. They incorrectly state that the significance level of Pollutants A and B (i.e., their t-statistics) would not be affected by measurement error. This is wrong, as my own numerical experiments and analyses of others demonstrate.
2. They also state that CM and $PM_{2.5}$ would have similar measurement errors. This is wrong: ambient concentrations of CM are much less uniformly spread over space than $PM_{2.5}$ -- this is even one of the reasons Schwartz and others have given for why we should control $PM_{2.5}$ and not CM!

When measurement error of $PM_{2.5}$ is acknowledged to be smaller than measurement error of coarser particles, and we are concerned that both might be culprits, we are clearly looking at Case 3, and the result is that the coarser fraction ("pollutant B"), might be falsely deemed insignificant. In other words, if you correct the factual errors in their example, you actually disprove the key conclusion of their paper: their analysis does not provide strong evidence that the fine fraction has more effect on health than the coarse fraction of PM.

Question 3. Your statement alludes to a critique of the risk estimates in the draft *Staff Paper*. Were your comments addressed in the final *Staff Paper*?

No. The final *Staff Paper* retains the same basic problems that I raised in my comments on the draft *Staff Paper*. The crux of my concern was with the final summary tables showing the levels of excess deaths projected under alternative PM standards. These tables provide a point estimate and a range that is called a "90% credible interval" for the estimates. The terminology and text suggest that this range reflects the results of a full uncertainty analysis. It does not. Each range reflects only the statistical confidence interval from a single study. That was the case in the draft *Staff Paper*, and it is the case in the final *Staff Paper*. No change was made.

Both the draft and the final *Staff Paper* provide several sensitivity analyses and discussion of uncertainties in the text leading up to those summary tables. The reader gets the impression that lots of careful uncertainty analysis is behind those summary tables. But even if some uncertainty analysis has been done on the side, it is not reflected in the summary tables. The final *Staff Paper* is worse than the draft in this way, because it provides even more complex discussions of "integrated uncertainty analyses" in the general text...and then the final "90% credible interval" does not reflect these analyses *at all*.

HOW STATISTICS CAN MISLEAD PM POLICY A Case of Smoke and Mirrors?

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March 10, 1997

SYNOPSIS AND IMPLICATIONS

New air quality standards for fine particulate matter ($PM_{2.5}$) have been proposed by the U.S. Environmental Protection Agency. The proposed standards are to address concerns that low ambient concentrations of fine particles (commonly described as smoke or soot, but actually a far more complex class of pollutants) may be a significant source of increased health risks. These concerns derive from statistical, epidemiologic studies, with little compelling scientific evidence supporting a causal relationship. This paper focuses on several key limitations that apply to all of the available epidemiologic studies. These limitations have been acknowledged, but the potential degree of error that they may cause is not widely recognized. As we will demonstrate, realistic situations could cause study after study, in widely varying locations, to find a statistically significant relationship between PM or $PM_{2.5}$ and health effects, even if PM is completely innocent. At the same time, true culprits, whether some other pollutant(s) or some other common aspect(s) of our environment, could be deemed "innocent" by epidemiology, even if researchers have explicitly included data on these culprits in their analysis.

In this paper, we endeavor to communicate both to those well-acquainted with the epidemiologic analyses and to a non-technical audience. We explain the causes of several common problems with pollution exposure estimates, and illustrate how these complications can cause epidemiology to generate completely misleading conclusions. We hope that this paper will enable all types of readers to understand intuitively how likely these problematic conditions might be, and how seriously they might be misleading many participants in the $PM_{2.5}$ policy debate.

1. INTRODUCTION AND OVERVIEW

What is the statistics debate about?

The U.S. Environmental Protection Agency (EPA) has proposed a new set of national ambient air quality standards for particulate matter.¹ These proposed standards would augment the current standards, which are based on concentrations of particles measuring less than 10 micrometers in diameter (PM_{10}), with additional standards regulating the concentrations of particles measuring less than 2.5 micrometers in diameter ($PM_{2.5}$). The foundation and rationale for these new standards, as set forth by EPA, are based primarily on a number of epidemiologic studies. By contrast, there is currently a lack of scientific understanding regarding the toxicological and physiological mechanisms which could lead to adverse health effects resulting from particle concentrations below the current PM_{10} standards. This lack is widely acknowledged, even among members of the EPA's Scientific Advisory Committee² and in EPA's own *Criteria Document*.³

The PM epidemiologic studies have, for the most part, revolved around statistical analysis and interpretation of health effects data and their relationship to measures of outdoor ambient air pollution. The potential pitfalls of such analyses, particularly when corroborating scientific understanding is lacking, have been well documented in the scientific literature. Statistical analysis can only go so far. It can point out associations between different factors, in order to direct attention to the factors which may be the most important. However, it is important to remember that a statistical association is not the same thing as a causal relationship. Just because two phenomena seem to vary together or have similar behavior does not mean that one is causing the other to behave in this way. Other mechanisms may be responsible. To be confident in assuming causality in a health- $PM_{2.5}$ association, we also need corroborating evidence or reasoning from physiological studies or other external sources.

In the debate over the evidence for new PM standards, some attention has been given to two concerns that we will address in this paper: the impact of observation errors (also commonly referred to as "measurement errors"), and the difficulty of separating out the roles of interrelated pollutants and other environmental considerations in a statistical analysis. Lipfert and Wyzga have written several technical papers on these issues, and have pointed out that the most worrisome situation is the combination of both concerns.⁴ Schwartz *et al.*,⁵ is the only original epidemiologic paper to have actually attempted to estimate the potential effects of "measurement error" in complicating the pollutant-separation task. However, the discussion in that paper focuses on the least problematic aspects of such errors, makes a couple of factual mistakes in its analysis, and thus prematurely dismisses measurement error as unimportant.⁶ Most other PM epidemiologists have acknowledged difficulties in separating the roles of PM from other pollutants, but for the most part, the PM epidemiologic studies have not even had data on many of the possible contributing pollutants.

Unfortunately, the technical aspects of the "measurement error" issue are so complex that it is very difficult for even technical readers to identify the flaws in the Schwartz *et al.* analysis. Our goal in preparing this paper was to describe these complicated effects in terms that will bring this issue to life for a wider range of concerned individuals. This paper uses

simple examples to illustrate how one could be completely misled by statistical analysis when there are data problems that are endemic to the PM epidemiologic studies. We hope this paper will enable a larger number of people to be able to judge for themselves whether the potential "measurement error" and "confounding" are worthy of greater attention than they have received to date.

How "wrong" can the statistics results be?

The data difficulties which arise for the statistical methods of environmental epidemiology can lead to erroneous conclusions. For example, one can be misled into believing that there is no "safe" level of a particular pollutant, below which no adverse health effect occurs, when in fact a safe level does exist. Even more significantly, one could also be misled into believing that one particular pollutant is so strongly associated with the incidence of adverse effects that it must be "causing" those effects. Such strong and persistent associations might occur even if a pollutant, in reality, has absolutely nothing to do with health effects. These startling errors of interpretation can result under conditions that may well describe the current U.S. ambient environment.

The essential problem is that discrepancies exist between what pollution monitoring instruments measure in a single location, and what individuals throughout a wide region around that monitor are actually exposed to. These observation errors distort the data and can mask important trends or relationships. In addition, when more than one pollutant is present (as is true for any real-world situation), and we don't *a priori* know which pollutant may be creating the observed health effects, it may be difficult or impossible to identify the culprit(s) using statistics, particularly if some pollutants have more observation error than others. Although we will work through this in intuitive terms below, Table 1 provides a quick synopsis of the biases that will appear in statistical results for the "simple" situation where there are only two positively correlated pollutants. Clearly, Case 1 in Table 1 (where exposures to an innocent pollutant are estimated with less error than for the culprit pollutant) is the situation that is of greatest concern, because this situation poses a substantial risk that the statistical bias will create a picture completely at odds with the actual reality. However, note that biases are present in all of the circumstances where there are positively correlated pollutants and measurement errors.

Table 1. Possible Measurement Error Conditions for Two Positively Correlated Pollutants, and Potential Resulting Epidemiologic Errors

	Which pollutant (A or B) is true culprit	Difference in measurement error	Resulting bias in statistical results
1.	A is innocent; B is culprit	A has smaller meas. error	Strong chance A would be falsely accused; Strong chance B would be falsely deemed insignificant.
2.	A is innocent; B is culprit	B has smaller meas. error	Some chance A would be falsely accused; Some chance B would be falsely deemed insignificant.
3.	Both A and B are culprits	A has smaller meas. error	Magnitude of A's role will be overstated; B's role will be understated and B may be falsely deemed insignificant.
4.	Both A and B are culprits	B has smaller meas. error	A's role will be understated and A may be falsely deemed insignificant; Magnitude of B's role will be overstated.

What are the policy implications of misleading statistics?

Given that the presence or absence of these types of biases have not been adequately explored to date for PM, one might feel little confidence that the proposed PM_{2.5} regulations would target the real culprit. This makes setting regulations like playing a classic Shell Game, where a pea is placed under one of a group of identical shells, which are then moved around. The customers try to guess the right shell, and usually lose. EPA is betting on the PM_{2.5} shell, but there are many other shells in this game that have not yet been dismissed by the epidemiology. We currently have little assurance that the EPA guess will be correct.⁷

One might feel even less confidence that the proposed PM_{2.5} regulations would generate benefits anywhere near the magnitude that EPA and others have estimated. Even if PM_{2.5} were accepted as a cause of premature mortality, the chances that it is the *sole* culprit being reflected in these studies is very dubious. EPA's risk and benefits analyses presume that the statistical relationships between PM_{2.5} and health effects have no biases, and are subject to no confounding.⁸ The potential for substantial errors in the statistical results (which this paper will illustrate) casts much doubt on EPA's estimates for the benefits of the proposed PM_{2.5} standards.

Guide to the rest of this paper

In the rest of this paper we will work through the issues that have been mentioned above step by step. First, we will show how distorted estimates of pollutant exposures can result from common problems in air pollution measurement (Section 2). Next, we explain how distorted data estimates can create bias in statistically-inferred relationships (Section 3). Then, to illustrate how these problems can result in serious policy mistakes, we present an example that deals only with a single pollutant, and show how its health-effects relationship can become obscured (Section 4). However, even more serious mistakes can result when inaccurate pollutant exposure data is combined with multiple, correlated pollutants. This example, which illustrates a situation such as Case 1 in Table 1, is the core of this paper (Section 5). We provide a discussion of what EPA and researchers have said and currently seem to perceive about the potential for these types of errors (Section 6). We conclude with a review of the policy implications of the current state of information regarding potential health effects of PM (Section 7).

2. WHAT DATA QUALITY PROBLEMS ARISE IN AIR POLLUTION MEASUREMENT?

Observation Error

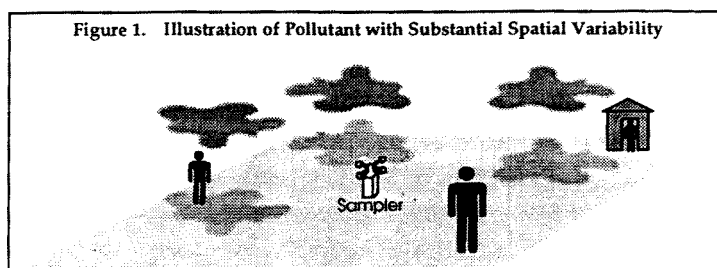
The epidemiology studies for PM are based on simultaneous measurements, or "observations" of health effects, PM, and various other contributing factors (sometimes, but not always including other air pollutants). For health effects, the observations are hospital admissions, deaths, or some sort of other measure of adverse health effects. For air pollutants, the observations are in the form of monitored ambient concentrations (i.e., how much of a particular pollutant is present in a given amount of outdoor air). Air pollutant observations are collected with scientific sampling instruments, usually on an hourly or daily basis. The monitors are usually in a fixed location, and often are part of the network of monitors being used to determine a region's compliance with air quality standards. As such, they tend to be located in parts of a city expected to have high pollutant levels. The monitors tend to be between 10 and 50 feet above ground, whereas people are mostly exposed much nearer ground level.

While these monitored ambient air pollutant data are convenient for epidemiologists, they clearly are not the actual exposures of individuals, which would be the correct information for estimating the true relationship of each air pollutant with public health. These monitor data are being used as a convenient method for approximating estimates of actual individual exposures. Even if they serve as a good approximation for some individuals, they can be a poor approximation for many more individuals throughout the entire associated metropolitan region. On this basis alone, the PM data for all of the epidemiology studies have a substantial source of error in them. This is sometimes called "exposure misclassification," or "non-representative sampling." It is a very important component of the so-called "measurement error" problem.

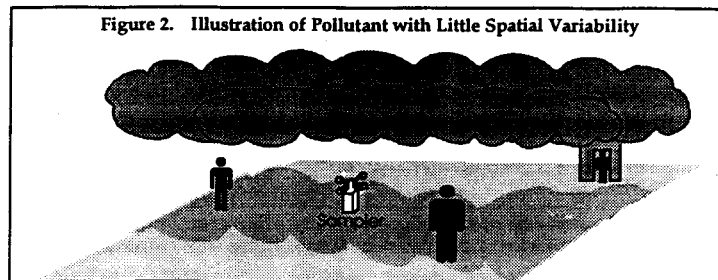
Another source of error comes from the fact that ambient monitors can themselves be inaccurate. Often this is what people think is meant by the term "measurement error." For clarity, we will use the term "instrumentation error" to refer to this specific type of data distortion. While it seems that it might be a smaller source of error than exposure misclassification, instrumentation error is not insignificant for many pollutants.

In this paper, we use the term "observation error" to reflect the combination of all sources of differences between the monitored ambient concentration and the actual pollutant exposures of the population in the area. The sources of the observation error do not matter in terms of their statistical consequences. All that matters is that observation errors exist. However, it is important to understand how large these observation errors might be, and also to understand the ways in which they might be different for different pollutants that could be included in the analysis.

For example, consider Figure 1, which shows a number of individuals at different locations throughout a wide region (such as a full metropolitan area), as well as a single sampler at a single location. Figure 1 shows localized areas of high and low pollution levels interspersed over the region. Different individuals, as well as the sampler, may be exposed to substantially different concentrations, depending on their specific locations. This non-representative situation means that the observation error is probably high, regardless of the accuracy of the instrumentation. This could be the case for coarse particles, which settle out fairly close to their sources, or for some gaseous pollutants, such as carbon monoxide, which rapidly convert to non-active forms such as carbon dioxide.

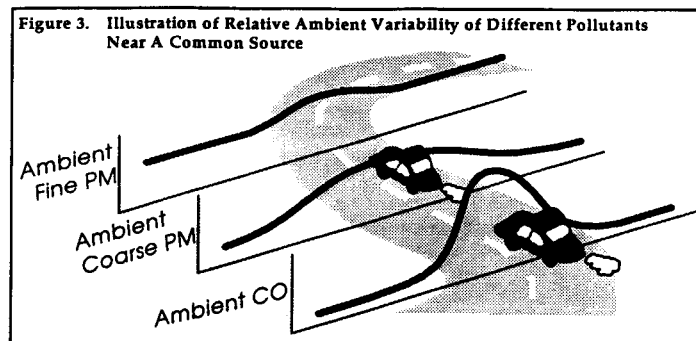


There is always some spatial variation in outdoor ambient concentrations, but it is a matter of degree. Figure 2 shows an example where the pollutant is much more widely dispersed. This could represent, for example, fine particles, which, because of their small size, remain suspended for a long time in the atmosphere, and therefore tend to be distributed more evenly over a wide area.⁹ Secondary products of emitted gases, such as sulfates, nitrates, and (to a lesser degree) ozone, also tend to have relatively little spatial variability, partly because they come from many sources in many directions. Because concentrations are similar throughout a wide region, the sampler measurement may be fairly representative of the "true" concentration to which most individuals are exposed *when they are outdoors*. If indoor concentrations (where most people are exposed for the majority of the day) were to reflect outdoor concentrations, observation error might be fairly low for a pollutant with little spatial variability and good instrumentation accuracy.



However, the majority of people spend most of their time indoors, and the difference between indoor and outdoor concentrations is a major reason why we can expect all epidemiologic studies that use ambient monitored concentrations of pollutants to be subject to substantial observation error.

The reality of significant amounts of observation error is important to understand, but it is equally important to understand that the degree of observation error can be very different for different types of pollutants, even on a much smaller spatial scale. Figure 3 shows qualitatively how differently concentrations drop off in the area adjacent to roadways, which are major sources of many of the possible culprit pollutants. Roadways are sources of levels of carbon monoxide (CO) from vehicle exhaust, and of coarse particles from the dust kicked up by spinning tires. They are also sources of fine particles from evaporation of fuels, and from exhaust.



CO concentrations fall off fairly rapidly away from the traffic as carbon monoxide is transformed into carbon dioxide (CO₂) before it can travel very far. Coarse particles fall out of the atmosphere after a relatively short time, although perhaps not quite as rapidly as CO. The fine particles tend to drop off less rapidly (and some are even created at a distance when evaporated volatile gases convert to secondary organic particles). Thus, people who spend much of their time adjacent to roadways may experience high exposure to all three of these pollutants. People who live relatively close to major roadways may experience similar exposures for coarse and fine particles, but less CO than the first group. People who live in adjacent areas several blocks away from any major roadways may experience levels of fine particles similar to the other groups, but quite different levels of coarse particles or CO. In the absence of instrumentation error, ambient concentration data from a monitor sited by a roadway probably would provide exposure estimates for CO and coarse particles that have greater observation error than for PM_{2.5}, even for a population confined to a small radius of just a few miles. In the epidemiologic studies, a single monitor is used to approximate exposures as much as 50 or more miles away.

Further, different pollutants have differing abilities to penetrate indoors. Ambient PM_{2.5} seems to migrate indoors and remain elevated to a greater extent than other ambient pollutants. Thus, fine particles may be subject to less overall observation error than other pollutants. As we will see later, this could be one reason why PM might have stronger health effects associations than other pollutants, yet not be the sole or key culprit.

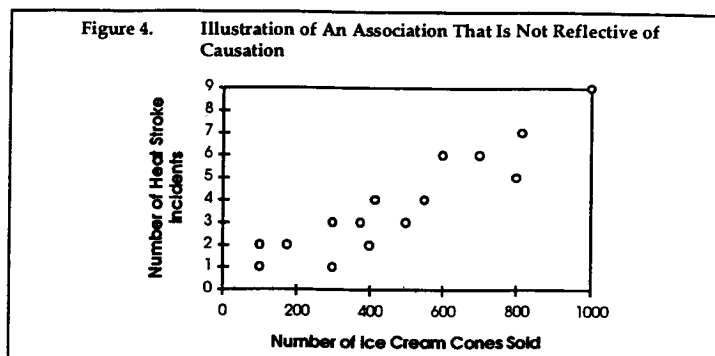
How large might observation errors be in the PM studies? The scientific papers indicate that errors of over 100% *just due to spatial variability in outdoor concentrations* may be realistic for some pollutants.¹⁰ Accounting for indoor-outdoor differences would augment the error levels much further. And instrumentation error might be yet another source of large errors. Not only may the observation errors be large, but they can differ greatly from pollutant to pollutant.

Correlated Pollutants

Another important complication in environmental epidemiology is the presence of correlated pollutants. This is also referred to as "collinearity" or "confounding variables." If two phenomena are correlated, it means they tend to move in step with each other. In statistical analyses with strongly correlated input data, it is possible that data on one possible causative agent might be a good substitute for data on another possible causative agent, because the correlation tends to give them similar patterns with respect to the phenomenon that one wishes to predict. It is as if one phenomenon serves as a mirror for observing the other. The clarity of the mirrored image improves as correlation increases to the maximum of 1.0.

A simple example of this mirroring effect is as follows. Suppose we obtained data on the number of ice cream cones sold on a particular day, and the number of people who suffered heat stroke on that same day. And suppose we put the data for several different days on a graph, as shown in Figure 4. Just looking at the figure, it appears that the two phenomena are related in some way. As ice cream sales go up, so do the number of heat stroke deaths. This is

called "association" between the phenomena. But does this association mean that eating ice cream increases the risk of heat stroke? Of course not. There is obviously an underlying factor that was *not* considered, namely, the temperature during the day. High temperatures would cause both higher ice cream sales and a higher risk of heat stroke. Ice cream sales are *associated* with heat stroke, but are not *causing* heat stroke.



The error in this example is rather obvious because we have a good mechanistic understanding of how heat stress occurs. But the example illustrates the danger of assuming that association is the same as causality without other supporting information about the *existence* of the relationships that we might be trying to estimate with statistics. Statistics can never "prove" causality; this must be established both from the statistical evidence as well as other corroborating evidence, such as information supporting a specific, plausible mechanism for relating cause to effect.

Air pollutant emissions are correlated because they tend to be generated by the same basic activities. As a result, the correlations of ambient concentrations of PM, PM_{2.5}, CO, NO₂, VOCs, and SO₂ tend to be relatively high (e.g., above 0.5 on a scale of 0 to 1).¹¹ There is a good chance that data on any one air pollutant could mirror one or more other pollutants. As we will see, in circumstances like this, *which* pollutant would appear to have the most significant and consistent relationship with health may be determined more by its relative observation error than by its actual contribution to the health effects in question.

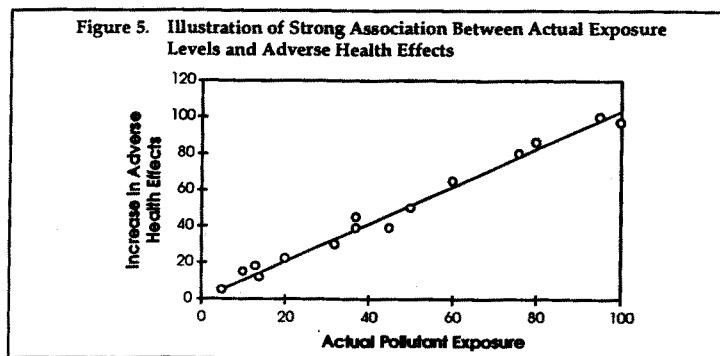
3. HOW DO DATA QUALITY PROBLEMS AFFECT THE STATISTICAL ANALYSES OF EPIDEMIOLOGY ?

What is epidemiology?

Epidemiology is the study of the occurrence of disease in populations. It is primarily a statistical science, attempting to find correlations and associations between various factors and using them to predict how the disease may occur or spread under specified conditions.

A common tool in epidemiology, and the one used in the PM health effects studies, is "regression analysis." Regression analysis can be thought of as "fitting a line" (or other shape of curve) to observations on two or more phenomena. This is most clearly visualized on a plot, such as Figure 5, where the two phenomena are pollutant exposure and adverse health effects. The circles represent the observations, and the line represents the "best-fit" relationship from the regression. (A perfect fit would have all points exactly on the line.) The regression estimate provides not just evidence that an association exists, but a quantitative estimate of how much the health effect changes when the associated agent increases. Thus, the relationship that would be estimated for data in Figure 5 is often called a "dose-response" relationship.¹² The slope of the fitted line or curve is used to generate an estimate of the "relative risk" due to a specific amount of increase in exposure.

Note that the terms "dose-response" and "relative risk" seem to carry a causative implication, even though the quantitative relationships being estimated still reflect only statistical associations.



What does statistical significance mean?

Statistical significance reflects how well the data actually conform to the specific relationship estimated by a regression, or the regression's "goodness-of-fit." The most commonly used overall measure of a regression's goodness-of-fit is the "coefficient of determination," more commonly called " R^2 ." The higher the R^2 , the better the model fits the data. The R^2 cannot be larger than 1.0; at an R^2 of 1.0, the data fit the relationship perfectly (e.g., in Figure 5, all the observed data points would lie exactly on the predicted line).

Statistical significance also gives us an idea of the individual importance of various possibly explanatory phenomena in contributing to the overall fit. This is most often judged by a "t-statistic," which is calculated for each potentially associated agent included in the regression. Essentially, the higher the t-statistic, the more significant the variable. Roughly speaking, t-statistics below 2.0 are getting into the range of borderline significance. The highest t-statistics give us an idea of what the primary drivers *may* be. However, statistical significance does not tell us anything about causality: it only tells us which data have the strongest association with the phenomenon being explained.

As we will see in the next two sections, the R^2 and t-statistics may fool us into drawing wrong conclusions about dose-response relationships when there are observation errors and correlations among data being used in the regression analysis.

How does observation error affect epidemiologic relationships?

Returning to the case of air pollution, let us look at how the observation errors that we described in Section 2 can affect the "line-fitting" that goes on in epidemiologic studies. For example, return to Figure 5, which evidences a strong trend in the relationship between actual exposures and health effects. If we had to estimate each of the actual exposures in Figure 5 from a central ambient monitor, each data point would be replaced by one that has some error. The errors will tend to be random, probably in both directions, and the ambient concentration data will thus distort the underlying actual exposure data in random ways.

This can be visualized as moving the *exposure* points of Figure 5 right or left, to higher or lower *ambient monitored concentrations*. Figure 6 provides an illustration. The top part of Figure 6 shows the data of Figure 5, and the arrows show specific observation errors for each exposure value. The bottom part of Figure 6 shows the resulting data for ambient concentration versus health effects.¹³ The underlying relationship does not emerge as clearly once observation error is included. Depending on the amount of observation error, the true trend may appear much less discernible or even disappear entirely, obscuring relationships that might be evident if exposures did not have to be approximated by monitored ambient concentrations.

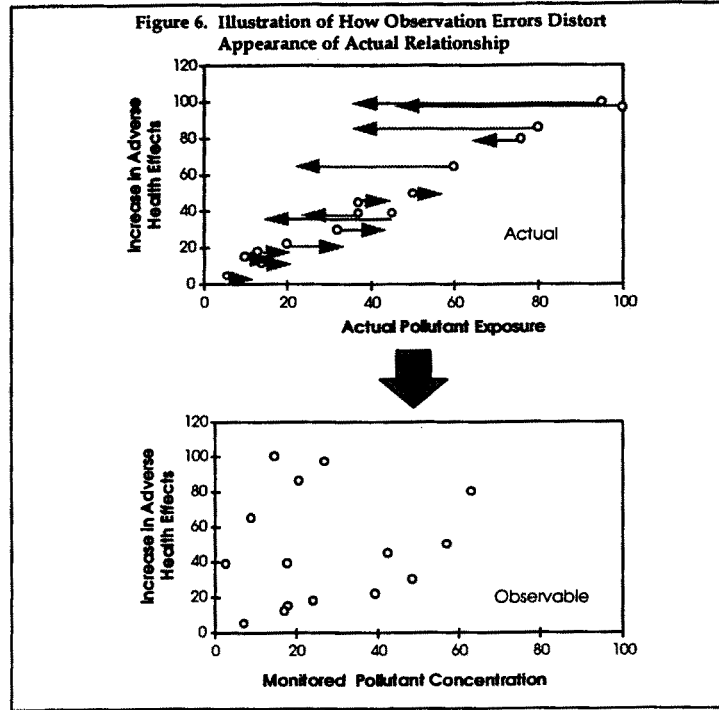
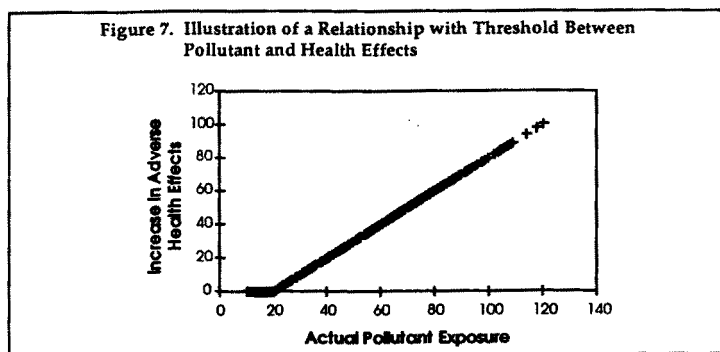


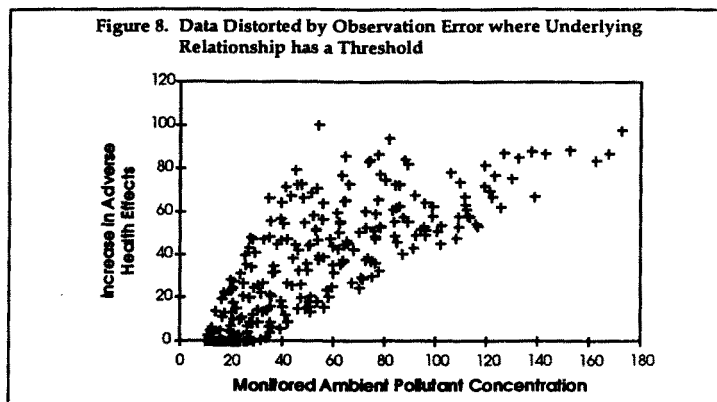
Figure 6 is a case where observation error is applied only to a single pollutant with a very simple dose-response relationship. The examples that follow in Sections 4 and 5 demonstrate how important this kind of distortion can be when the actual relationship is more complex, and also when there are multiple correlated pollutants in addition to observation error.

4. OBSERVATION ERROR CAN OBSCURE THE SHAPE OF A DOSE-RESPONSE RELATIONSHIP

Observation error does not necessarily obscure the presence of a relationship, but it can affect our ability to determine the real shape of the relationship. One example which has been mentioned extensively in the PM debate is the inability to detect a "threshold," below which no adverse health effects occur. We will illustrate how this can happen. Suppose that the true relationship between pollutant exposure and increased health effects involves a threshold at 20 units of the pollutant. Below 20, there are no increased adverse health effects, while above the threshold, the effects rise with each increase in amount of pollutant exposure. Figure 7 depicts 300 data points according to this relationship. If we could actually measure each of these data points, a regression would easily estimate the relationship with a threshold at 20.



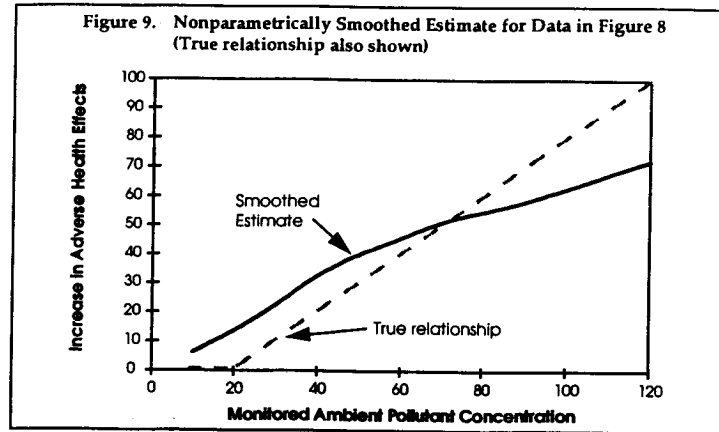
But now let's consider what happens if our observations of actual exposure are not perfect due to instrument inaccuracies and non-representative samples from ambient monitors. In Figure 8, we have used a random number generator to add a modest amount of observation error to the 300 exposure data points in Figure 7, to reflect how ambient concentration data might look, given the actual exposures.¹⁴ The observed data are much more scattered.



What would epidemiology tell us if we purposely tried to seek out the threshold that we know is underlying the data in Figure 8? One way to do this is to run several different regressions, each with a different threshold level assumed, and see which regression gives the best fit. ("Best fit" is usually determined by looking for the highest R^2 , as described in Section 3.)

We tried assuming three different levels for the threshold (0, 10, and 20), then used regression analysis each time to estimate the rise beyond the threshold. For a threshold of 20, the R^2 was 0.56; for a threshold of 10, the R^2 was 0.65; and for no threshold, the R^2 was 0.68. The correct relationship (threshold of 20) has the *worst* fit to these data, while the best-fitting relationship involves no threshold at all!

The difficulty in detecting a threshold has been widely acknowledged by EPA and by researchers performing these studies. To try to address this issue, several researchers have used a more sophisticated statistical technique called "nonparametric smoothing". This technique does not require the slope of the relationship to be constant, and thus it has been suggested that this technique would be able to show evidence of a threshold if the slope were to flatten out as lower concentration levels were reached. Figure 9 shows the nonparametrically smoothed curve applied to the data in Figure 8.¹⁵ Just as with the linear regression, there is no sign of a threshold in the relationship. In fact, the relationship seems to get *steeper* at lower pollutant concentrations. This shows that nonparametric smoothing is subject to the same measurement error difficulties as linear regression.

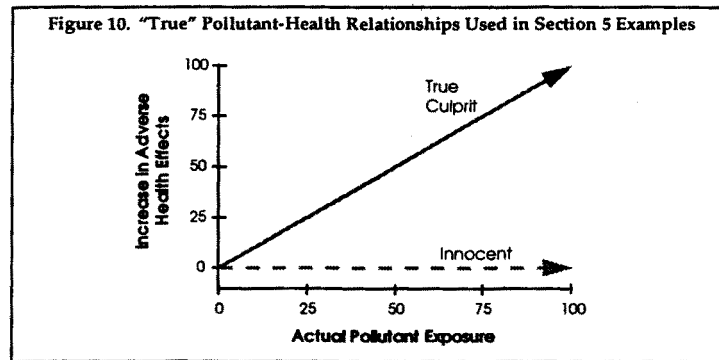


Observation error, which is pervasive in real-world analyses, has caused statistical estimates to erroneously suggest that a threshold does not exist. This is a serious error because it means that we might conclude that there is no safe level of this pollutant, when in fact there is a safe level. Uncertainty in whether a threshold may exist for $PM_{2.5}$ has enormous impact on EPA's benefits estimates. Sensitivity analyses have demonstrated that assuming a threshold in the range of 20 to 30 $\mu\text{g}/\text{m}^3$ (24-hour average $PM_{2.5}$ concentration) reduces the large benefits that EPA has estimated for the proposed regulation to a much smaller level, orders of magnitude less.¹⁴ This amount of uncertainty implies that benefits of the proposed regulation could be well below the cost of the regulation.

5. OBSERVATION ERROR CAN CAUSE THE WRONG POLLUTANT TO BE IDENTIFIED AS THE CULPRIT

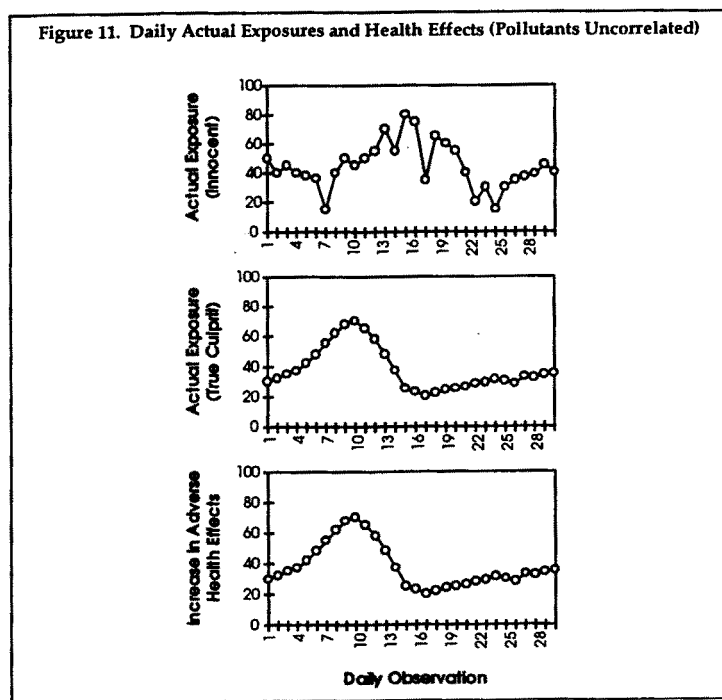
The threshold-disappearing act illustrated in Section 4 has been mentioned by several authors to point out the significant mistakes that can occur when observation error distorts the data. However, there is an even more serious problem that can arise when we consider more than one pollutant, each having observation errors. In this case, we might also reach erroneous conclusions about the presence or absence of *any* relationship. This section presents an example to illustrate how this can happen.

The example of Section 5 is built around two hypothetical pollutants, one "Innocent" and one "True Culprit." All of the health effects data that follow in this section are created using the "true" relationships that True Culprit causes increased adverse health effects in a deterministic linear manner, while Innocent has no effect on health at all. In terms of "dose-response," the relationships are set up as shown in Figure 10.

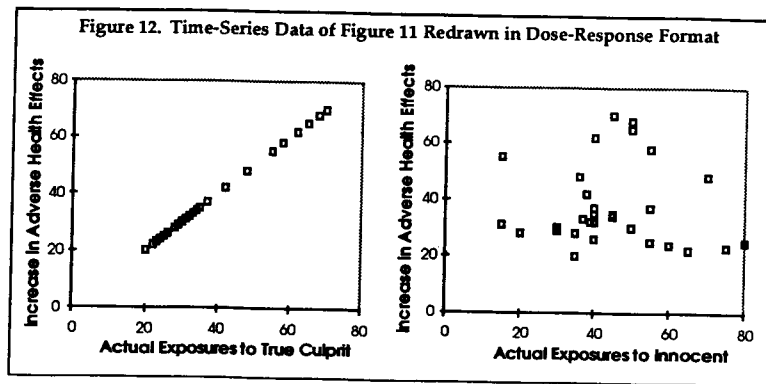


The right answer — without observation error and without correlated pollutants

First, let's say that True Culprit and Innocent are not correlated and that there is perfect measurement and representation of exposures (i.e., no observation error). Then if we were to graph many days' worth of "true" data consisting of the actual exposures to both pollutants, and observed increases in health effects, we might find a situation like Figure 11, where we can see how each pollutant and incremental health effects change over time. Since True Culprit alone causes the health effects, we see that its concentrations and the health data have similar trends. If we did an epidemiologic study trying to relate health effects to both pollutants, the analysis would select True Culprit as having the better association with health effects, and would indicate that Innocent has no effect. Epidemiologic methods can give us the right answer when the available data are "clean" and exposures are uncorrelated, as in this example.

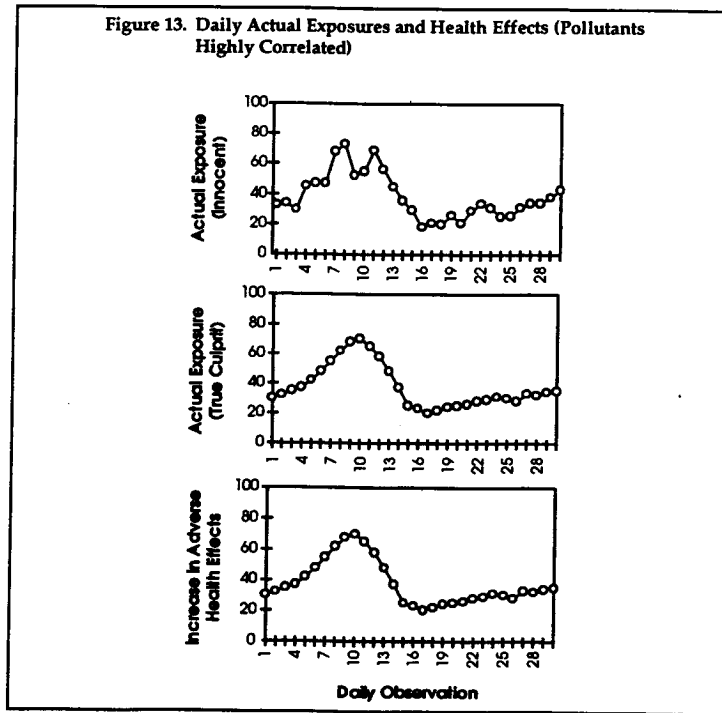


The linkage of the data in Figure 11 to a dose-response relationship can be seen by regraphing the same data points in the format shown in Figure 12. The left side of Figure 12 shows data relating True Culprit and health. The right side shows data relating Innocent and health. If you think of the regression as simultaneously fitting a dose-response slope for each pollutant, it is easy to see how the regression would generate the correct dose-response for True Culprit, and correctly not attribute any health effects role to Innocent. In other words, these data clearly reflect the dose-response relationships that we started with (i.e., Figure 10).



The wrong answer if the analysis is not careful — when there is only correlation

Now, let's suppose that the two pollutants are highly correlated, as is the actual situation for criteria air pollutants. For example, Figure 13 shows a case with high correlation between exposures to True Culprit and Innocent. The correlation is not perfect, but if True Culprit is high, then Innocent is very likely also to be high, and similarly if True Culprit is low, then Innocent is also likely to be low.¹⁷ Now, we see that both pollutants track along with health effects pretty well. If we had data only on Innocent, we would likely determine that it has an association with health. However, the statistical methods still can correctly pick out True Culprit as having the best association, as long as it is included in the regression as well as Innocent. In this case, the statistical association for Innocent changes a lot when True Culprit is in and not in the regression. This is an example of simple confounding. If data are available *and used* for all pollutants, the confounding often can be detected. More intractable problems start to arise when True Culprit and Innocent have observation errors, as we will next see.



The wrong answer even with a careful analysis — when there is observation error too

Now, let's assume our estimates of exposure are better for Innocent than for True Culprit.¹⁴ Suppose that True Culprit has a larger observation error, up to 100% around the actual exposure, while Innocent has a smaller error, only up to 25% around the actual exposure. (Other combinations of observation error assumptions will be considered later in this section.) We let the computer generate these errors randomly, and used them to distort the actual exposure data shown in Figure 13. The resulting possible set of "monitored ambient pollutant concentrations" are shown in Figure 14.¹⁵

Because of the observation errors, the previously clear pattern of a relationship between True Culprit and health effects is obscured. The Innocent pollutant is also affected, but to a smaller extent because of its smaller error. Looking at this picture, which tracks health effects better? Innocent does. Innocent's lesser observational error allows its ambient concentrations to mirror exposures to True Culprit better than do True Culprit's own ambient concentrations! Regression analysis sees it the same way, and indicates that Innocent has a better association, giving it a higher significance in terms of the t-statistic and a greater contribution to the adverse health effects.

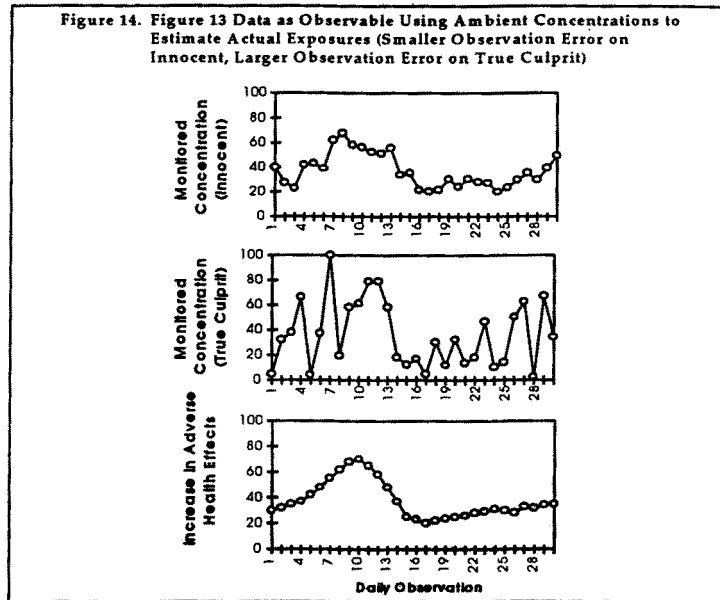
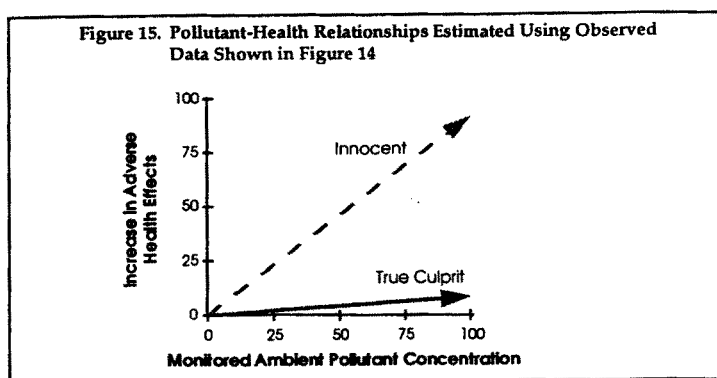


Figure 15 shows the "dose-response" slopes that are estimated by a regression analysis of the data in Figure 14. These regression results are a complete reversal from the true underlying relationships of Figure 10! Further, the t-statistics, which are measures of significance for each pollutant's association, are 7 times higher for Innocent than for True Culprit, again indicating that Innocent is better associated with the increase in adverse effects. The R^2 , the measure of the overall goodness-of-fit in this regression analysis, has a value of 0.76, which would typically be considered quite good. All of the statistical evidence suggests that Innocent is responsible. Thus, observation error, pollutant correlation, and a straightforward statistical procedure have led us down the wrong path toward a conclusion which is the exact opposite of the truth.

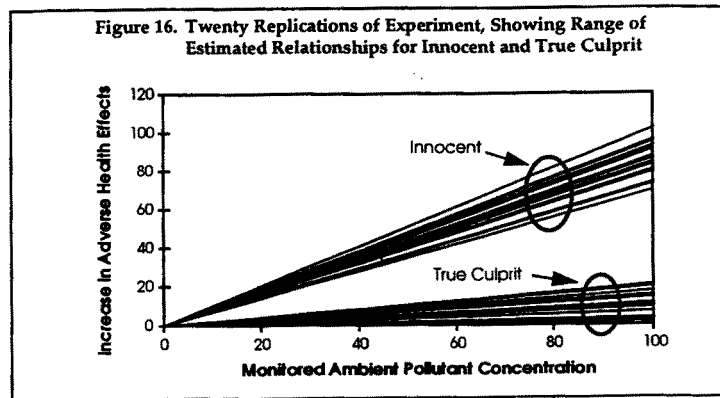


The larger errors in True Culprit have masked its effect, while Innocent, which is correlated with True Culprit and thus has its general pattern, has smaller error which does not mask the pattern. The regression sees enough of the same pattern in Innocent and health effects to conclude that Innocent is a better predictor. There is nothing technically "wrong" with the regression. Indeed, if we do not change the way emission sources currently operate, it is true that the ambient measurements of Innocent would be a better "predictor" of the adverse health effects of True Culprit. But this does not mean that if we controlled Innocent, then health effects would be correspondingly reduced. That would only happen if the association found between Innocent and health were a causal relationship.

The greatest problem with this spurious association of Innocent with health is that it remains stable whether or not True Culprit is added into the regression. Further, if only True Culprit is included in the regression, the R^2 falls to zero. True Culprit is the pollutant that seems to have a highly unstable association and very little explanatory power on its own. Thus, unlike in the simple confounding case, the usual methods for checking for confounding no longer function well when there are observation errors as well as strong correlation among pollutants.

The wrong answer —over and over again

The results in Figure 15 were based on one particular way that the randomly assigned observations errors might come out. We let the computer randomly pick this set of errors, after which we did the regressions using the resulting "ambient concentration data." Is the extreme divergence of the estimated relationship from the true relationship just a rare outcome, or one that would have a strong likelihood of occurring? To find out, we re-ran this experiment 20 times, letting the computer randomly pick new observation errors each time, and then re-doing all of the epidemiologic analyses using the new data. Only the potential size of the observation errors was kept the same. Figure 16 illustrates the estimated "best-fit" relationships for all 20 cases. Each time, the same type of situation arises, with Innocent being considered more significant than True Culprit, a stronger contributor to increased adverse health effects, and having a more robust association. Our example was not a fluke; the same misleading and erroneous conclusions emerge, regardless of the particular way in which the observation errors come out.



So far, all of these experiments have been based on errors that are less than 25% of true values on Innocent and less than 100% of true values on True Culprit. While we have explained how observation errors can easily be larger than we have used here, we have little specific quantitative knowledge about them at this point in time. Thus, it is important to explore the potential for such misleading results over a range of other levels of errors. Tables 2 and 3 shows the results of similar experiments with four other levels of error. We did experiments 20 times over for each assumed level of errors. The averages of each set of 20 regression estimates appear in Table 2. Table 3 summarizes the one experiment out of the 20 which is closest to giving the "right" answer (i.e., that True Culprit is the estimated true culprit).

For either view of the results, once observation errors for True Culprit diverge from actual exposures by as much as 50% of the actual exposure level, epidemiologic techniques may start giving us the wrong answer. For example, when errors are within 50% of actual exposure levels for both pollutants (the middle row of the tables), their relative estimated effect and the relative significance levels are about equal. While True Culprit would likely be identified as associated with health effects, Innocent runs an equal chance of also being identified as associated. Further, if a highly correlated Innocent has substantially less observation error, the True Culprit observation errors do not even have to be near the 50% level for this mistake to emerge. For example, when the True Culprit error is 50% but Innocent has only a 10% error (the fourth row of the tables), Innocent stands out as much more strongly associated than True Culprit. Thus, True Culprit could have an error much less than 50% before it would start to appear more associated than Innocent.

Actual observation errors may be much larger than those shown in Tables 2 and 3, although we presently have little knowledge of the relative magnitudes of the errors for different pollutants. The correlations between the pollutant concentrations used in the analyses to generate these tables are between about 0.4 and 0.9, which is strong correlation, but also appears to be consistent with actual ambient pollutant conditions (see note 11).

Table 2. Average Estimated Relationships Derived From True Relationships of Figure 10, for Varying Amounts of Observation Error.

Measurement Error (%)		Average Over 20 Replications				
Innocent	True Culprit	Innocent		True Culprit		Goodness of fit (R ²)
		slope	t-statistic	slope	t-statistic	
0	0	0.00	infinite	1.00	infinite	1.00
10	10	0.15	2.6	0.85	14.7	0.98
50	50	0.46	5.5	0.51	6.1	0.72
10	50	0.77	10.3	0.21	3.0	0.88
25	100	0.85	14.0	0.11	2.1	0.75

Table 3. Most "Correct" of 20 Estimated Relationships Derived From True Relationships of Figure 10, for Varying Amounts of Observation Error.

Measurement Error (%)		Least Convincing of the 20 Replications				
Innocent	True Culprit	Innocent		True Culprit		Goodness of fit (R ²)
		slope	t-statistic	slope	t-statistic	
0	0	0.00	infinite	1.00	infinite	1.00
10	10	0.04	0.6	0.94	16.6	0.98
50	50	0.36	4.0	0.61	6.1	0.65
10	50	0.63	8.3	0.31	4.7	0.89
25	100	0.73	15.6	0.21	4.7	0.82

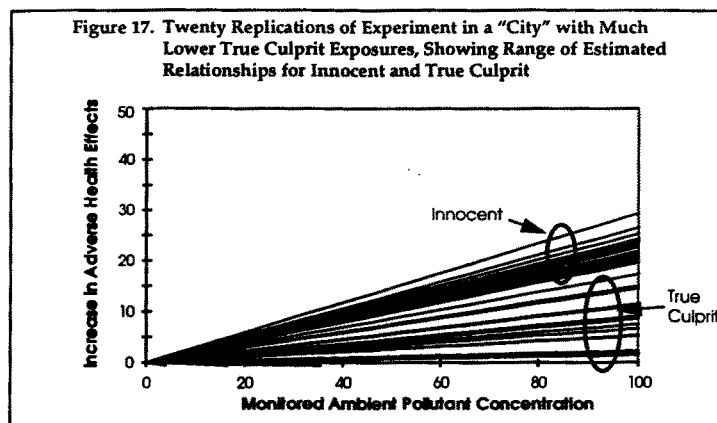
6. WHAT CAN BE DONE TO MANAGE THE POTENTIAL FOR THESE PROBLEMS IN THE PM STUDIES?

The examples in Sections 4 and 5 illustrate how several specific data problems (i.e., instrument inaccuracy, pollutant data not being fully representative of actual personal exposures, and correlations in exposures to many pollutants) can cause seriously misleading conclusions in epidemiology studies. More sophisticated statistical techniques than we have described do not remove the potential for making these mistakes in epidemiology. Essentially, these techniques smooth the data to try to remove much of the up-and-down fluctuation not associated with pollutants and other explanatory variables. Most of the fluctuations that smoothing techniques address are not even present in our very simple and “clean” hypothetical examples. However, we explored two different types of smoothing in the course of our analysis, to make sure that these conclusions would not be avoided through more complex regression methods. For example, we applied a moving-average to smooth out fluctuations in the time series in the Section 5 example. We also used nonparametric smoothing²⁰ to provide a more flexible estimate of the shape of the relationship in the Section 4 example. Neither effort removed the misleading conclusions that we have illustrated.

EPA’s *Staff Paper* recognizes the potential pitfalls of epidemiology and suggests that robustness of the observed associations for alternative regression specifications will help support the case for causality. EPA argues that if the association can be demonstrated under several different conditions (such when a correlated pollutant is included and then removed from the regression) then it is not likely that the PM-health association is actually due to one of these potential confounders. The techniques cited by the *Staff Paper*, (and applied in part in a few of the actual studies) can help identify situations where correlation is a potential problem. These techniques do not, however, address the problems that we have shown to occur when correlation is combined with observation error (and particularly when different pollutants are subject to different amounts of observation error). For example, in the regressions with data in Figure 14, all of the alternative specifications would suggest that Innocent has the stronger and more robust relationship with health effects. Hence, we reiterate and emphasize the *Staff Paper*’s own statement that “a comprehensive, formal treatment of exposure misclassification studies of PM and other community air pollutants is an important research need.”²¹

The *Staff Paper* and other sources have also argued that consistency of association across different cities would allay concerns of confounding and support the argument that the PM-health association is causal. The argument is that if associations of a particular pollutant with adverse health effects appear consistently in different geographical areas that have widely varying levels of other potential culprit pollutants, the association is less likely to be a statistical artifact and more likely to be indicative of true causality. We have done additional experiments to test for the persistence of the false association between health effects and Innocent in situations with substantially different levels of the culprit pollutant. We found this suggested approach non-compelling as a way of enhancing the argument that the PM associations with health are causal.

For example, we took the data used in Section 5's examples, but made the levels of True Culprit one-quarter the level in those examples. This reduced the levels of incremental health effects too, since the "true" relationships of Figure 10 were not altered. We left the levels of Innocent unchanged. After applying the same differential measurement errors, we again came up with the reversal of reality, as illustrated in Figure 17. Of course, the slope of the relationship being falsely attributed to Innocent is reduced in a measure comparable with the decrease in True Culprit's levels, but Innocent still is consistently stronger in its association than True Culprit. In fact, the t-statistics for the Innocent-health association remained stable while the t-statistics for the True Culprit's association halved. Thus, although the magnitudes of the slopes became more similar, statistical significance measures actually *reinforced* the likelihood that True Culprit would be dismissed as a potential causative agent.



Thus, if an innocent pollutant is showing a non-causal association with health, variations in average concentrations of the true culprit will result in variations in the estimated relative risks as one moves from location to location, but that variation will not necessarily be sufficient to exculpate a falsely charged innocent pollutant. Further, the degree of variation in any criteria pollutant among the U.S. cities studied to date may not be sufficient to reveal much variability. For example, some have suggested that the consistent presence of the PM-health association across cities with different levels of other potentially confounding pollutants (e.g., for Philadelphia PA, St. Louis MO, Salt Lake City UT, Orem UT, Santa Clara CA, and Knoxville TN) is a sign that no other pollutant is likely to be the key culprit. We reviewed ambient criteria pollutant levels (CO, PM₁₀, NO₂, SO₂, and O₃) in these cities and found that the four-fold range in True Culprit (i.e., from Figure 16 to Figure 17) may be overly large. Across these six cities, the largest range in any of the pollutants was about three-fold (for NO₂), and pollutant levels were within a factor of 2 or less for all the others.²⁷ At most we might expect the PM-health relative risk to be altered by a factor of 2, and the estimated relationships do vary by

about this amount. Interestingly, we also found that the “clean” areas of Utah actually had the highest levels of CO, even as they had low levels of the other pollutants. Thus, if it were to happen that ambient CO were adversely affecting health, one should not expect to see *any* decline in the relative risk associated with PM in Orem or Salt Lake City compared to other cities.

Thus, there is likely to be cross-regional consistency of the PM relationship, even if PM is innocent. If a non-PM culprit (e.g., one or more of CO, NO_x, SO₂ or O₃) is causing health effects in our environment, and if that culprit has more observation error than PM (which may be true of any of them), we still should not expect the PM-health association to vary among these cities any more than it already does. PM (“smoke”) could be serving as a statistical mirror for other culprits in every one of these locations.

7. THE PROPOSED REGULATIONS ARE A GAMBLE

Statistics can mislead. Statistics and epidemiologic analysis are tools for detecting association. These methods are best used to test for relationships that have already been hypothesized by other, generally mechanistic reasoning. Statistics also can help direct attention to possible areas for more focused scientific investigation. But statistics can only rarely be relied on to establish causality, and then only when the data are very "clean," not subject to significant observation errors, and not subject to high degrees of correlation with other possible causative factors. By contrast, the claims of causality in the case of $PM_{2.5}$, and the consequent proposed regulations, are based almost entirely on statistical studies that rely on very "messy" data.

EPA claims to have taken the resulting uncertainty into account when selecting the new proposed standards. But let's look at that a little more closely. How did EPA determine how much uncertainty exists? Careful examination of its methods shows that the only uncertainty which it considers is a "90% confidence interval" on the slope of the regression-based "dose-response" relationship between fine particles and adverse health effects.²³ The 90% confidence interval is derived directly from the t-statistic that we have shown to be potentially subject to very substantial biases. This is tantamount to assuming away all of the potential biases that this paper has illustrated. As we have seen in our example, observation error and correlated factors even cause statistics to implicate the wrong pollutant, while exonerating the real culprit. Clearly the benefits and risk analyses that EPA has published do not properly reflect the nature and degree of uncertainty that we currently face.

Basing new regulations upon this type of evidence amounts to playing a shell game with high economic stakes. There are plenty of ways that statistical results can trick us into selecting the wrong shell when working with data and evidence such as we currently have. There is no guarantee, not even a reasonable assurance, that the regulations are targeting the right pollutants. We may spend billions of dollars controlling fine PM, only to find that we are not achieving the health benefits that EPA has suggested we can expect. Meanwhile, true culprits may continue unabated.

Notes

- ¹ 61 *Fed. Reg.* 65637 ff., December 13, 1996.
- ² G. Wolff, "The Scientific Basis for a Particulate Matter Standard," *EM*, October 1996, pp. 26-31.
- ³ "... no credible supporting toxicological data are yet available that provide insight into potential mechanisms. ... little non-epidemiologic evidence is presently available to support or refute a causal relationship ... between low ambient concentrations of PM and observed increased mortality or morbidity risks." (USEPA, *Air Quality Criteria for Particulate Matter*, EPA/600/P-95/001cF, April 1996, p. 13-31.)
- ⁴ F. Lipfert and R. Wyzga, "Air Pollution and Mortality: Issues and Uncertainties," *Journal of the Air and Waste Management Association*, Vol. 45, pp. 949-966, 1995.
F. Lipfert and R. Wyzga, "Uncertainties in Identifying 'Responsible' Pollutants in Observational Epidemiology Studies," *Inhalation Toxicology*, Vol. 7, pp. 671-689, 1995.
- ⁵ J. Schwartz, D. Dockery, and L. Neas, "Is Daily Mortality Associated Specifically with Fine Particles?" *Journal of the Air and Waste Management Association*, Vol. 46, pp. 927-939, 1996.
- ⁶ For a detailed explanation of the problems in the Schwartz *et al.* analysis of measurement error, see "Dr. Anne Smith's Responses to Questions from Senator Inhofe", February 25, 1997, a written supplement to the testimony of Dr. Anne E. Smith, February 5, 1997, to the U. S. Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety on "Scientific Issues Surrounding the Proposed PM_{2.5} Standard." (Copies of this supplement can be obtained from the office of Senator Inhofe, or from Decision Focus Incorporated).
- ⁷ Additional comments along these lines have been presented in "Playing a Shell Game with Public Policy: The Proposed PM_{2.5} Standard," comments by Dr. Anne E. Smith at the EPA Public Hearings, Boston, MA, January 14, 1997, and in Dr. Anne E. Smith's February 5, 1997 testimony to the U. S. Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety on "Scientific Issues Surrounding the Proposed PM_{2.5} Standard."
- ⁸ The degree to which these assumptions overstate the risk (and hence benefits) estimates is demonstrated in A. Smith, "Comments on Risk Analysis in EPA's Draft *Staff Paper* for a Particulate Matter National Ambient Air Quality Standard," (Formal written comments to EPA prepared on behalf of the Utility Air Regulatory Group,) Decision Focus Inc., June 6, 1996.
- ⁹ EPA's *Criteria Document* (referenced in note 3) agrees that "PM_{2.5} particles are generally likely to be more uniformly distributed than coarse particles within an urban airshed. ... size-specific fixed-station ambient PM measurements generally approximate total ambient fine PM exposure more closely than coarse PM exposure." (p. 13-52)
- ¹⁰ For example, an EPA study of the St. Louis area revealed carbon monoxide (CO) concentrations ranging from 0.2 to 2 parts per million (ppm) within a ten-mile radius. This represents about a -75% to +150% range around the average concentration of 0.8 ppm. T. Karl, "A Study of the Spatial

Variability of Ozone and Other Pollutants at St. Louis, Missouri," *Atmospheric Environment*, Vol. 14, pp. 681-694, 1980.

- ¹¹ For example, a draft HEI report found the following annual average correlations between ambient monitored TSP and other ambient pollutants in Philadelphia: TSP to CO = .48; TSP to NO₂ = .67; TSP to SO₂ = .65. Correlations were even higher within individual seasons. (J. M. Samet, S. L. Zeger, *et. al.*, *Air Pollution and Mortality in Philadelphia, 1974-1988*, Report to the Health Effects Institute on Phase IB: Particle Epidemiology Evaluation Project. Draft. Department of Epidemiology and Biostatistics, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, MD, March 25, 1996.)
- ¹² Technically, Figure 5 actually shows an "exposure-response" relationship. And for regressions using ambient monitor data, one is technically estimating a "concentration-response" relationship, which is even less close to a true dose-response. However, all of these fitted relationships are commonly called dose-response relationships, and we continue to use that colloquial terminology in this paper.
- ¹³ The errors for Figure 6 were made to be uniform over the range +/- 100%. That is, the observed measurement could be as low as zero or as high as twice the true concentration, with no particular value more likely than any other within this range. The distortions used in Figure 6 were actually generated randomly on a computer for this example; we did not predetermine the errors to give this particular picture.
- ¹⁴ The ambient concentrations are uniformly distributed within 60% of the true exposure value, i.e., the observations are selected randomly somewhere between 40% and 160% of the true value. Observation errors could easily be this large or larger, for reasons articulated in Section 2.
- ¹⁵ A. Smith, "Comments on Risk Analysis in EPA Draft Staff Paper for a Particulate Matter National Ambient Air Quality Standard," (Formal written comments to EPA prepared on behalf of the Utility Air Regulatory Group.) Decision Focus Inc., June 6, 1996.
- ¹⁶ The technique used is Loess smoothing as described in W. Cleveland and S. Devlin, "Locally weighted regression: An approach to regression analysis by local fitting," *Journal of the American Statistical Association*, Vol. 83, No. 403, pp. 596-610, 1988; and in W. Cleveland, "Robust locally weighted regression and smoothing scatterplots," *Journal of the American Statistical Association*, Vol. 74, No. 368, pp. 829-836, 1979. Our specific application (using a 70% data window for pollution), was styled after applications described in J. Schwartz, "Nonparametric smoothing in the analysis of air pollution and respiratory illness," *The Canadian Journal of Statistics*, Vol. 22, No. 4, pp. 471-487, 1994.
- ¹⁷ The correlation between actual individual exposures in Figure 13 is 0.9.
- ¹⁸ This is the situation that leads to Case 1 in Table 1.
- ¹⁹ The correlation between the ambient concentrations in Figure 14 is 0.56.
- ²⁰ See note 16.

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- ²¹ A. Smith, "Comments on Risk Analysis in EPA Draft *Staff Paper* for a Particulate Matter National Ambient Air Quality Standard," (Formal written comments to EPA prepared on behalf of the Utility Air Regulatory Group.) Decision Focus Inc., June 6, 1996.
- ²² Used data for years 1986, 1990, and 1995 by Metropolitan Statistical Area found in Table A-17 of USEPA, *National Air Quality and Emissions Trends Report, 1995*, EPA 454/R-96-005, Research Triangle Park, NC, October, 1996.
- ²³ USEPA, *Review of the National Ambient Air Quality Standard for Particulate Matter: Policy Assessment of Scientific and Technical Information*, (OAQPS Staff Paper), EPA-452/R-96-013, July 1996, p. V-43.

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Edited exclusively for scientists interested in environmental policymaking and policymakers interested in science

**The Real Particulate Matter Culprit:
EPA's Flawed Assumptions**

By Anne E. Smith
Vice President, Decision Focus Incorporated

On Nov. 27, 1996, EPA released a proposal for new National Ambient Air Quality Standards (NAAQS) for particulate matter smaller than 2.5 microns (m) in diameter, or PM_{2.5}. These NAAQS would supplement the existing PM₁₀ standards, which cover particles that are up to 10 m in diameter. The scientific foundations for the proposed new PM_{2.5} standards have an unprecedented level of uncertainty, and are generating substantial controversy. The debate is complex, but can be decomposed into three specific aspects of risk policy considerations: problems in the science; problems in the risk and benefits estimates; and problems in using the traditional NAAQS regulatory paradigm to manage this issue.

Evidence suggesting we should consider alternatives to the current PM₁₀ NAAQS standard consists of a series of epidemiologic studies in various urbanized areas that found a statistically significant association between monitored levels of ambient PM and measures of both mortality and morbidity. Of course, the potential effects on mortality are receiving the greatest attention. By epidemiologic standards, the relative increases in risk being estimated are fairly small (i.e., generally less than 20 percent, with some studies finding no significantly increased relative risk). However, if the incremental risk estimates are taken at face value, they may imply many thousands of premature deaths per year, which would hardly be considered a minor public health concern. For the most part, these epidemiologic studies are based on PM₁₀ data; the rationale for shifting to controls on PM_{2.5} is founded more on biological reasoning than on epidemiologic evidence.

To date, the bulk of the controversy has centered on perceived problems in the science. Basically, there are three scientific reasons to question whether a PM_{2.5} standard would generate the benefits that the epidemiologic studies might seem to imply. These considerations all stem from the fact that PM is a complex mixture of many types, sizes, and physical states of chemical compounds which come from a wide range of sources. The only shared characteristic among all constituents of PM is that they are not gaseous: they include everything from windblown dirt to aerosols formed from solvent vapors. A look at the three basic scientific issues produces the following observations:

Science Issues

(1) Researchers have thus far been unable to find toxicological evidence against PM, or suggest a plausible biological mechanism, at the level of credibility required by the peer reviewed "Criteria Document," which is the summary of the science on which ambient air quality standards must be founded. Since PM has many different constituents, and the mix varies, perhaps the constituent that has the potency to cause health effects has yet to be studied. However, the inability to elicit significant and consistent biological responses to any of the key constituents in ambient PM is certainly troubling. If ambient PM is having such large impacts on mortality rates in so many locations, one would expect that adverse biological changes would be observable in laboratory studies at much higher concentrations. Toxicological evidence suggesting plausibility of biological effects is present for other criteria pollutants (e.g., ozone, carbon monoxide, sulfur dioxide, nitrogen oxides, etc.).

(2) The absence of supporting scientific evidence suggests that the statistical associations may not be evidence of a causal association of mortality with PM. If that is the case, what else could explain the consistency of the statistical results in so many locations? A major concern with epidemiologic studies is the potential for statistical confounders to be at work. Given that most of the criteria pollutants have common sources, and that weather can substantially affect pollutant concentrations, it would be quite possible for PM to be mirroring the effects of another causative factor, such as another pollutant or a weather-related effect. Are the statistical associations between PM and mortality consistently derived with sufficient controls for these other potential influences? In short: no. For example, the Health Effects Institute reanalyzed data for one of the key epidemiologic studies and found that other criteria pollutants not in the original study also are associated with

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mortality, and it is not possible to discriminate among them.

Some have countered that the case for causality is nevertheless supported by the consistency of the PM-mortality association across many locations with varying levels of the other pollutants. How could the PM association be attributed to carbon monoxide or ozone if it appears in locations where carbon monoxide is low, and in locations where ozone is low? The flaw in the counterargument lies in another data problem in these studies, known as "measurement error." Some pollutants are easier to measure accurately than others. For example, volatile compounds such as many organic compounds are difficult to capture, while solid particles common in PM10 are easy to trap and do not disappear. Another important form of measurement error in all of the PM statistical studies comes from the use of ambient monitoring data to approximate the exposures of individuals to ambient pollutants. Some pollutants, such as coarser particles and carbon monoxide, tend to stay relatively close to their sources, while other pollutants, such as fine particles, spread out more evenly in space, including indoors. The monitored data on the latter pollutants are probably much better estimates of actual individual exposures than monitored data on the former. Statistical theory tells us that when two pollutants are correlated, a better measured but non-causal pollutant could appear more significant than a poorly measured causal pollutant.

Because of the ubiquitous automobile, we know that other pollutants such as carbon monoxide, NOx and VOCs were present in all of the cities studied, even if concentrations may not appear high at monitored locations. These pollutants may be subject to greater measurement error than PM10 or PM2.5. Differences in measurement errors for the many pollutants would tend to be consistent across locations, regardless of the level of other pollutants. Thus, some caution is still warranted in drawing a causal conclusion on the basis of consistency across locations. Similarly, measurement error may be one explanation for results that indicate that PM2.5 has more explanatory power than PM10: exposures to PM2.5 are probably much better approximated by a central monitor than PM10 exposures. Even if PM2.5 and PM10 were to have equivalent potential to degrade health, PM2.5 might consistently appear to have greater statistical significance.

(3) Knowledge about specific constituents of PM2.5 is lacking. Epidemiologic studies use only a generic measure of pollution — the total mass of all types of particles — and therefore none of the studies can tell us what role individual constituents may be playing in the observed associations. Even if we assume a causal relationship between fine particles and mortality, we still lack any evidence about what the fine particle culprit might be. The statistics shed no light on this. So what should we control to achieve reduced risks from PM2.5? An honest answer is: We still don't really know.

Thus, problems in the science on PM2.5 have created a very complex public health risk picture. We think air pollution might be shortening thousands of lives, but we aren't sure. Statistical correlations may be telling us something about an overall effect, but nothing about how to attribute the effect to individual air pollutants. I have heard people compare the current uncertainty about PM health impacts with that of tobacco smoke's health impacts. The argument is made that we still don't know what constituent of tobacco smoke is carcinogenic, but we can agree that enough information exists to know how to reduce risks. The analogy is a poor one because all of the constituents in tobacco smoke come from a single source: the tobacco itself. Thus, even though we are uncertain of the exact culprit, we do know of a single control strategy — quitting — that will reduce the unknown culprit with certainty. There are no comparable PM control strategies that can reduce most or all of the types of PM constituents through a single control action.

Risks and Benefits

The use that some people have made of the tobacco smoke analogy hints at the kinds of problems that exist in the risk and benefits assessments associated with the PM2.5 NAAQS proposal. The uncertainties in this problem are not as simple as "How many lives might be lengthened for a given reduction in PM2.5?" We also need to ask, "What pollutant needs to be reduced to achieve a risk reduction?" The critical uncertainty in this problem goes deeper than the numerical estimate of a dose-response slope or threshold. The critical uncertainty is the qualitative identification of the culprit. I have compared this risk situation to the classic "Shell Game" where a person tries to guess which of several shells is covering a pea.

How have these uncertainties been addressed? The regulatory process so far has tried to stick to a business-as-usual approach. That is, following completion of the Criteria Document, EPA developed the strongest case it could to argue that the evidence is sufficient to assume a causal relationship between PM2.5 and mortality. Some scientists

Problems in the science on PM2.5 have created a very complex public health risk picture.

Commentary

accept EPA's argument and some do not. However, once this case was made, EPA then developed its risk and benefit estimates for alternative PM2.5 standards using the epidemiologic relationships as if they could be interpreted as quantitative dose-response relationships for PM2.5. In effect, EPA has implicitly assumed that the Shell Game-like uncertainties do not exist. The decision to set a PM2.5 standard assumes away the possibility that the culprit is any of a number of other reasonable environmental candidates. This decision also assumes away the likely possibility that some types of fine particles are more potent than others.

What we have on our hands is a case study in the pitfalls of incorporating epidemiologic evidence into regulatory risk assessments. EPA's "Staff Paper" for the PM2.5 standard reports a risk analysis for alternative PM2.5 standards as they might be applied in Philadelphia and Los Angeles. The dose-response curve for each health endpoint is based on the relative risk estimated from a single study. Besides the singularly large assumption that mortality has a causal relationship with PM2.5 and with PM2.5 alone, the assumptions that are implicit in the risk estimates are strikingly strong:

- (i) EPA assumes no threshold in the dose-response function, because no threshold was observed in the study. However, the Criteria Document acknowledges that epidemiologic methods would be very unlikely to ever observe a threshold, if one exists.
- (ii) EPA assumes that all PM2.5 constituents are equally potent, so that every control action implied by the rolling back of ambient PM2.5 is assumed to be rolling back the culprit constituent(s). However, the Criteria Document acknowledges that it is unlikely that all the constituents are equally potent.
- (iii) EPA assumes no biases exist in the estimated regression coefficient, and that all of the uncertainty about the numerical estimate of the slope is captured in the 90 percent statistically-derived confidence interval on that slope. This is in spite of a Criteria Document discussion of likely causes of bias in such slope estimates due to known data limitations.

As a result, it is not at all surprising that EPA's Staff Paper finds that the risk estimates "suggest a pattern of a continuum of decreasing risk with lower levels of alternative PM2.5 standards, extending over and likely below the range of 65 to 25 $\mu\text{g}/\text{m}^3$ PM2.5" [Staff Paper p. VII-27]. EPA's assumptions made this result a foregone conclusion. The more important question that goes unanswered is, "What do the risk estimates look like under alternative assumptions about the real dose-response relationship behind the epidemiologic results?"

To answer this question, I developed a risk model that could reproduce the EPA risk analysis results. I then explored alternate assumptions, first adding only a single additional form of uncertainty: a probability distribution on the possible level where a threshold may occur. I used the possible range on a threshold value discussed by EPA in the same report. What I found was that the revised "90 percent confidence interval" on risk reductions almost encompassed zero incremental risk. Clearly, if we were also to incorporate uncertainties due to the following considerations — results from alternative studies, potential biases in epidemiologically-derived slopes, the risk that the implementation strategy may not target the actual culprit constituent, and the potential that PM2.5 is serving as a surrogate for some other pollutants — we would have a very different sense of the "90 percent confidence interval" on risk reductions from a PM2.5 standard.

The benefits for the proposed standard are estimated in the "Regulatory Impact Analysis" to be between about \$50 billion and \$150 billion per year. These are based on the same flawed dose-response method, with the exception that even the statistically-derived confidence intervals on dose-response slope have been removed. The range here is just two point estimates from two different studies: one from a time-series ("short-term") study and one from a cross-sectional ("long-term") study. Clearly these benefits estimates contain enormous uncertainties. There may be a reasonable chance that PM2.5 is causing mortality, but there also is a reasonable chance that the benefits of a PM2.5 standard will be very small or even zero, even if PM2.5 does contain the culprit constituent.

Flawed Regulatory Paradigm

The problems for the PM2.5 standard are more than just analytical. There are problems with the regulatory paradigm itself. The new standard, if adopted, stands out as one of the most costly that EPA has ever proposed. In fact, EPA's official cost estimate of about \$6 billion per year is only for "partial attainment." The actual costs of achieving the standard are estimated to be so much higher that the "Regulatory Impact Analysis" has assumed that dozens of areas would more likely just remain out of attainment. In making policy judgments for a program of this size, it is essential that the supporting risk and benefits analyses not be predicated on assumptions that we know the culprit and that our implementation strategy will surely target that culprit. The full range of uncertainties needs to be expressed in all of the communications about potential risk reductions or benefits from the PM2.5 standards.

The PM NAAQS problem demands more than careful delineation of uncertainties, however. When the cost estimate for a standard is kept within "reasonable" bounds by explicitly assuming that the standard is not likely to be met, we should recognize that the proposal is setting goals rather than standards. The concept of a health-based standard is starting to weaken in the

case of the PM_{2.5} NAAQS, partly because there is a poor scientific basis for it, and partly because there is a poor chance that it would be attained. We need to consider whether an alternative risk management paradigm would be more appropriate. A draft letter circulated by Senator John Chafee (R-R.I.) (*Risk Policy Report*, Dec. 20, 1996, p5) has raised the possibility that considerations other than health may need to be considered in setting this NAAQS. I think even more direct management of the Shell Game-like uncertainties may also be warranted.

What do I mean by this? The essence of the Shell Game is that we cannot at this moment set a specific ambient standard and be assured that the actions leading to attainment with that standard will reduce the public health culprit. The separation of implementation from standard setting is a venerated tradition for NAAQS, but it may be working against effective risk management in this situation. In the face of this Shell Game, however, there may be some precautions for which our nation is willing to pay, and we may be able to start to identify them through the following questions: What do the various unproved hypotheses suggest would be the most likely culprits? What control actions would most effectively address these culprits? Which potential culprits will not be reduced substantially by the ongoing control programs of the Clean Air Act? Where are the likely gaps in our existing protective programs and what are sensible and affordable ways to start to close those gaps? What research program would help us narrow down the list of potential culprits and ultimately be able to set a true health-based standard?

Rather than debating the question, "Are we willing to pay for a generic PM_{2.5} standard that may or may not protect public health?" we could more productively explore the question, "Are there better defined actions that will help close the control gaps and knowledge gaps in an efficient manner?" The latter approach may require more direct specification of implementation strategies and research plans than the traditional NAAQS process allows. However, it may be a more appropriate response to the circumstances than continuing to pretend that we can set a health-based standard when there is no sound scientific basis to identify the true culprit. We have already seen how the current interpretation of the NAAQS process has resulted in seriously incomplete estimates of risks and benefits. It also may be leading us down a regulatory path that provides less effective risk management than our nation deserves.

PREPARED STATEMENT OF DR. JOEL SCHWARTZ, ASSOCIATE PROFESSOR, DEPARTMENT OF HEALTH, HARVARD SCHOOL OF PUBLIC HEALTH, HARVARD MEDICAL SCHOOL

I have several points I would like to make today:

1. EPA is not out in front of the science on the proposed particle standard, but rather lags behind a number of governments in Western Europe and International Scientific Bodies. The proposed particle standard was approved by its own scientific review panel. Following those nations in reducing its particle standard will avoid tens of thousands of early deaths in the United States.

2. Substantial evidence exists that fine combustion particles of all types are associated with deaths, hospital admissions, and respiratory illness.

3. Despite claims to the contrary, recent toxicological studies show that animals exposed to combustion particles in controlled conditions exhibit the same effects seen in human epidemiology studies.

4. The focus on combustion particles, rather than on dust, is supported by physiology, toxicology, and epidemiology. This strategy avoids costs to control particles which have been shown not to affect public health.

Today, there is a strong scientific consensus that particulate air pollution at levels below the current EPA standard are associated with substantial increases in mortality and morbidity. Last year, the British Government's scientific panel reviewed the epidemiological studies of the association between particulate air pollution and daily deaths and found they were properly done, consistent across many cities, supported by morbidity studies, and concluded that it would be imprudent not to consider those associations causal. They recommended that the British government set a new particle standard at a level that is only one third of the current US standard.¹ The World Health Organization recently convened a panel of international experts to develop a particle criteria document. They also concluded that there is strong evidence that particulate air pollution below current standards is responsible for increased deaths, hospital admissions, and illnesses, and published dose-response relationships for countries to use in standard setting. These World Health Organization relationships predict that the proposed EPA standards will avoid tens of thousands of early deaths per year. A Swiss Government scientific review panel has likewise recommended a new particle standards be set at a level of one third of the current EPA standard. Despite obfuscatory arguments by industry-supported scientists, the Clear Air Scientific Advisory Panel voted to approve a proposed range of 12 to 20 $\mu\text{g}/\text{m}^3$ as an annual average standard for fine particles. The EPA proposal of 15 $\mu\text{g}/\text{m}^3$ is in the middle of this range.

The reason why so many scientific bodies have reached this conclusion is the vast scope of literature indicating that particulate air pollution has these effects. For example, studies have shown that increases in daily particle levels are followed by increases in daily deaths in Amsterdam, Athens, Barcelona, Basel, Berlin, Birmingham, Boston, Chicago, Cincinnati, Detroit, Dublin, Erfurt, Eastern Tennessee, London, Los Angeles, Lyon, Madison, Milan, Minneapolis, Mexico City, New York, Philadelphia, Provo, Rotterdam, Santiago, Santa Clara, Steubenville, St. Louis, Sao Paulo, Topeka, Valencia, and Zurich. Recent animal studies have corroborated these findings, showing toxic effects of fine particles, especially in sick animals.

Having failed to convince the scientific community and the established scientific bodies designated to review the merits of their case, industry has launched a lobbying offensive to convince political leaders and the general public with the same arguments that failed to sway a more technically sophisticated audience.

One common argument given is that even if particles are causing tens of thousands of early deaths per year, we should not regulate them because we do not know "which particles" to regulate. Absent that knowledge, we might waste money regulating the wrong source. I will comment on the scientific aspects of this issue. Airborne particles are a complex mixture of particles differing by size, chemical composition, and structure. Fine particles, which are the focus of this regulation, are almost entirely generated by combustion, that is, the burning of fuel or other high temperature processes that generate energy, propel automobiles, or produce products. Each combustion source, in itself, generates a complex mixture of particles. Hence control strategies to reduce exposure to fine particles will never focus on a specific particle, they will focus on sources. The question becomes, then, whether the health effects are due to the types of particles generated by one or only a few of the sources, and whether we might waste resources regulating sources that have little health impact.

¹Expert Panel on Air Quality Standards. Particles, Department of the Environment. London: HSMO, 1995; p.30.

Fortunately, the vast range of locations where airborne particles have been associated with increased deaths and hospital visits allows us to examine the association in locations where each of the major sources is the predominant source of fine particles. Sulfate particles from coal burning power plants predominate in the Northeastern US and Canada, and many studies have shown associations between those particles and daily deaths and hospital visits. But in Santa Clara CA, a winter time study by Fairley showed that particles that were predominantly wood smoke, with almost no sulfates, were also associated with more deaths, and wood smoke predominates in Spokane and Seattle, where particles were associated with increased hospital visits. In Los Angeles, Sao Paolo, and Mexico City, the predominant source is automobile emissions, in London today it is diesel exhaust, in Erfurt Germany and in Dublin it is coal soot, and airborne particles have been associated with increased deaths per day in all these locations. The epidemiologic data indicates that all of the major sources of airborne particles contribute to the excess deaths imposed on the public by particulate air pollution.

In toxicological studies, Godleski of Harvard has shown that exposure to either concentrated air particles from the Boston air (primarily sulfates from coal burning powerplants) or to resuspended fly ash from an oil boiler, killed rats with chronic bronchitis. These effects occurred at particle concentrations that were not extraordinary, but comparable to concentrations seen in U.S. cities. Costa's lab at the US EPA has also shown toxicity using either oil fly ash or concentrated particles from air in Washington DC (sulfates from coal) or a German city (traffic and industrial pollution).

EPA has proposed, with CASAC approval, to focus on the fine particles due primarily to combustion, rather than windblown dust, in tightening the particle standard. Industry critics have also challenged this decision. But EPA's focus on true "pollution" and not dust is supported by a study following the Mount St. Helens eruption, which showed very high concentrations ($10,000 \mu\text{g}/\text{m}^3$) of dust had little health effect. A Centers for Disease Control study of a dust storm in southeastern Washington State found little impact from an episode where particle concentrations exceeded $1000 \mu\text{g}/\text{m}^3$. In contrast, an episode of combustion derived fine particles at half those concentrations was associated with a substantial increase in daily deaths, hospital admissions, and ambulance calls in West Germany in 1985. The great air pollution episodes of the mid century (London in 1952, Donora Pa in 1948, and the Meuse Valley in Belgium in 1930) were all episodes of combustion related fine particles that occurred in stagnant air conditions which would result in low dust levels. And the increased deaths from all of these episodes are widely agreed to have been causal.

We also know that it is only the fine particles that can penetrate deep into the lung past our primary respiratory defense mechanisms. This is important because the studies of daily deaths and particulate air pollution show a much larger percent increase in pneumonia deaths than of all deaths. Pneumonia is a disease of the lower lung, to which fine particles but not coarse particles, penetrate. The increase in heart disease deaths also seems more plausibly related to particles that penetrate in the breathing region of the lung which is closely connected to the heart.

The animal data also clearly point to the fine particles as much more toxic than the coarse particles. When Dreher and coworkers at EPA placed fine particles and coarse particles collected from the air in Washington, DC in the lungs of animals, they found substantial toxicity from the fine particles, but little from the coarse particles. The same laboratory has shown that fine combustion particles can induce life-threatening heart arrhythmias in animals with chronic lung disease. Osornio-Vargas and colleagues at the National Institute of Health assessed the toxicity to lung cells of particles sampled from different areas of Mexico City. The particles from the northern part of the city, which were primarily from combustion were much more toxic than the particles from the south, which included much more dust.

Costa and coworkers have shown that the toxicity of airborne particles is related to the concentration of soluble metals on their surface, and that coarse particles have much lower concentrations of soluble metals than fine combustion particles. This may explain the differences in the toxicological data.

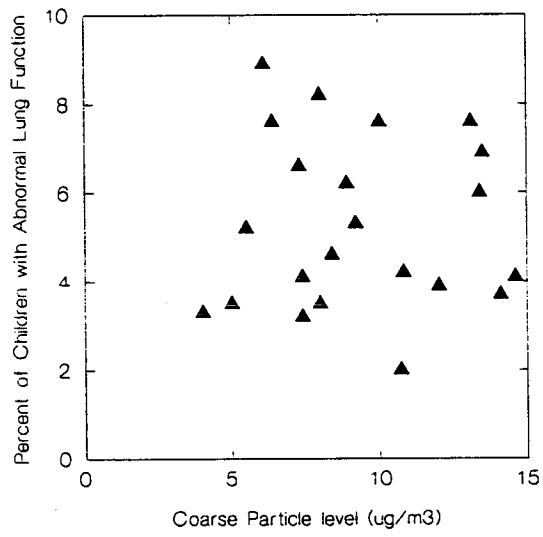
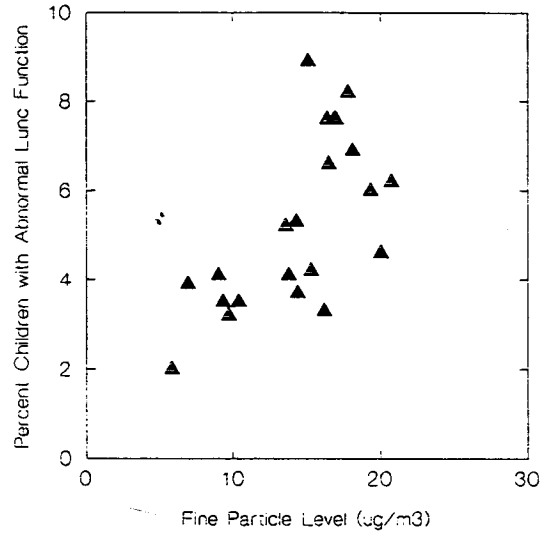
As noted above, Godleski has exposed rats to concentrated fine particles from Boston. The exposure averaged less than $100 \mu\text{g}/\text{m}^3$ over a 3-day period, but peaked at $288 \mu\text{g}/\text{m}^3$. While healthy rats were not affected 37 percent of the bronchitic rats died following this modest exposure. These results agree with the epidemiology studies which show the greatest increases in deaths occur in people with chronic lung disease. Even lower concentrations of fine particles from Boston air were associated with changes in electrocardiograms in healthy dogs. These electrocardiogram changes are known risk factors for sudden deaths. Again, the epidemiology studies have shown that these deaths are particularly affected by airborne particles.

Epidemiology studies also support the conclusion that the fine combustion particles, and not the dust, are responsible for the observed health effects. In 1994 Thurston and coworkers at New York University reported that coarse particles were not associated with hospital admissions for respiratory disease in Toronto, but that fine particles were. We reported the same results for daily deaths in six US cities last year. Hence the epidemiology is quite consistent with the toxicology, and what we know about the penetration of particles of different sizes into the lung.

Industry has argued that these epidemiologic results all derive from measurement error. These arguments about measurement error have been made consistently by Dr. Lipfert throughout the process of writing the EPA criteria document, and its review by CASAC. They represent nothing new, were available to CASAC when it approved moving to a fine particle standard, and are contradicted by the animal studies. The latest version of this argument suggests that we lose some of the coarse particles of our current monitors, but the amount varies from day to day. This will reduce the correlation of coarse particles with mortality. However, fine particles are also lost by current monitoring techniques. Because the monitors collect particles for 24 hours and then measure them, volatile chemicals on the fine particles often escape off the filters before the 24 hour period is up. Hence both measures are subject to measurement error, and it is not clear which is larger.

Other studies have looked at the effects of long term average exposure to fine versus coarse particles. This is important, because averaging over many measurements averages out the measurement error. For example, Figure 1 shows data from the 24 City Study, which was published last year. The percent of children (aged 8–12) with abnormal lung function in each town (after controlling for age, sex, height, and weight) is plotted against the mean concentration of fine particles in that town. A strong trend is seen, with the percent of children with abnormal lung function increasing threefold as you go from the less polluted to the most polluted communities. Figure 2 shows the same percentages plotted against the concentration of coarse dust particles. No evidence of any association is seen.

In summary, and international scientific consensus has emerged on the adverse effects of combustion related particles. This has resulted in widespread efforts to tighten airborne particle standards throughout the western world. The EPA proposal is not an attempt to push the limits, it follows conclusions by other scientific review bodies and governments.



PREPARED STATEMENT OF DR. RONALD E. WYZGA, BUSINESS AREA MANAGER FOR AIR QUALITY, HEALTH, AND RISK STUDIES, ELECTRIC POWER RESEARCH INSTITUTE

I am Dr. Ron Wyzga. I work for the Electric Power Research Institute (EPRI), in Palo Alto, California. The Institute, which is a voluntarily funded 501(c) organization operating in public interest by electric utilities, is over 20 years old and has an annual budget of approximately \$500 million. The Environment group is part of EPRI with an annual budget of approximately \$50 million; this is one of the largest privately funded health & environmental research organizations in the world. Within the Environment Group, I am responsible for air quality research, including research on the health effects of particulate air pollution. All EPRI health and environmental research is published and made available to the interested public, and researchers are encouraged to publish their results in the peer-reviewed scientific literature. Many of the particulate matter (PM) health studies cited in the EPA Criteria Document and Staff paper were funded or partially funded by EPRI, including much of the research undertaken at the Harvard School of Public Health on this issue.

Personally I became interested in the topic of PM and health while a graduate student at the Harvard School of Public Health. My doctoral dissertation in biostatistics covered this topic back in 1971. Since then I have been actively engaged in environmental health and statistics issues. I have co-authored a book and written over 40 papers that have been published in the peer-reviewed scientific literature. I have obtained many significant recognitions from my peers. I have served on and chaired subcommittees of the National Research Council, National Academy of Sciences. I have served or chaired several EPA Science Advisory Board Committees. I have also been appointed a Fellow of the American Statistical Association. The comments that I present today reflect my personal views and judgments as a scientist, who has worked in this area for over twenty-five years. These comments should not be construed to be the official opinion of my employer or of any associate.

Below I cite several studies and documents. In an effort to achieve brevity and avoid technical details, I do not include data or attach papers. At times, to be more understandable, I try not to use statistical jargon. I have the back-up technical material, which I would be happy to share with you if you desire.

SCIENTIFIC ISSUES

Several statistical studies suggest an association between particulate matter and health. I have authored some of these; EPRI has funded many more. Does this association mean that a reduction in particulate matter air pollution will lead to public health benefits? I believe the correct answer to this question is that no one knows. We have positive studies, but these results are tempered by the following issues, which are discussed in more detail below:

(1) Study results are not consistent. There are several studies which fail to find any significant positive association between health and particulate matter.

(2) Re-analyses of the data from existing studies do not support an unambiguous particulate matter-health association. The re-analyses by independent investigators do not agree with the original investigators' conclusions of a significant association between particulate matter and health. This is true whether the re-analyses have been funded by public (e.g., US EPA) or private entities.

(3) There is no one correct way to analyze data to determine the relationship between health and particulate matter. The results of these analyses differ according to the methods used. Hence flexibility in choice of analysis can influence the results in a way that invalidates commonly used statistical tests.

(4) It has not been possible in current studies to disentangle the effects of particulate matter air pollution from those of other pollutants and weather.

(5) There is an inconsistent relationship between the levels of particulate matter that people actually breathe and (a) the measure of particulate levels used in air pollution health studies as well as with (b) the levels of particulate matter that would be regulated.

(6) There is no accepted biological explanation for the results of the statistical models.

(7) If there is an association between particulate air pollution and health, there is no extant health information that suggests greater health effects associated with $PM_{2.5}$ (particulate matter less than 2.5 microns in diameter) than with PM_{10} (particulate matter less than 10 microns in diameter).

(8) To understand any health effects and to manage $PM_{2.5}$ concentrations, we need a more accurate definition of $PM_{2.5}$ than that to be measured by the proposed Federal reference method.

The studies are not consistent. The evidence for particulate air pollution health effects comes from epidemiology studies (studies of people in the real world), not laboratory or animal studies. Several epidemiology studies report no significant relationship between particulate matter and public health. There are negative studies; for example, studies by Styer et al. of Salt Lake City; Morris of Manchester, England; Roth of Prague, The Czech Republic; Burnett et al. of ten Canadian cities, and Abbey et al. of California. In addition, the recent APHEA study of the European Commission, found no significant relationship between PM and mortality in several Eastern European cities, where pollution levels were high. Why are these studies inconsistent with other studies that report a significant relationship between PM and mortality? The methods used in the positive and negative studies appear to be reasonable and suggest no obvious error. Is it chance or is there some explanation why positive results are found in some locations, but not in others?

Re-analyses of existing studies do not support an unambiguous particulate matter-health association. Several studies that have reported significant associations between particulate matter and health have been re-analyzed. By and large these re-analyses do not reach the same conclusions as the original studies. For example, under contract to U.S. EPA, Davis et al., at the National Institute of Statistical Sciences, re-examined daily mortality and particulate matter relationships in Birmingham, Alabama. The Davis et al. analysis tries to insure that the effect of hot and humid days is considered in any model trying to assess the influence of particulate matter on mortality. They conclude: "When we use the same variables as included by Schwartz, we obtain similar results to his. But when we use alternative models we obtain different conclusions. In particular, when humidity is included among the meteorological variables (it is excluded in the analysis by Schwartz), we find that the PM₁₀ effect is not statistically significant." Roth and Li in a study supported by EPRI similarly examined Birmingham mortality data, as well as hospital admissions data; they also could find no effect of particulate matter on health. The Health Effects Institute, in a project supported by the U.S. EPA and the automobile industry, verified the numerical correctness of the results of Dockery and Schwartz in Philadelphia, but they also tried alternative models in their research project and found it impossible to definitively link particulate pollution with increased Philadelphia mortality. After application of several models, they conclude: "We caution against using the model coefficients directly to estimate the potential consequences of lowering concentrations of the individual pollutants through regulatory measures; the pollutant concentrations are correlated and the estimates of their effects depend on modeling assumptions."

In a paper published in the journal *Epidemiology*, Moolgavkar and Luebeck presented an independent analysis of the relationship between daily air pollution and mortality in Philadelphia. They conclude: "[I]n Philadelphia, each component of air pollution, when considered alone, is an important predictor of mortality in at least one season. . . . When all pollutants are entered simultaneously into the model, however, nitrogen dioxide appears to emerge as the most important pollutant." In a second study Moolgavkar and his colleagues also "failed to replicate findings" of the study of the relationship between daily deaths and particulate air pollution in Steubenville, Ohio.

EPRI has recently sponsored a re-analysis of the relationship between daily respiratory hospital admissions and air pollution in Detroit. Joel Schwartz of Harvard had previously analyzed these data and found a statistically significant association between hospital admissions and particulate air pollution. He was kind enough to send his data to a group of statisticians at Stanford University. When they applied the same model as Schwartz, they obtained similar results. When they incorporated the potential influences of day of week into the model, particulate matter was no longer a significant predictor of hospital admissions. This is potentially important because hospital admissions vary by day of week. If they go down on weekends and pollution is lower on weekends, and if an investigator did not consider "day of week" in the model, then the investigator could wrongly attribute the effects of weekend behavior to pollution.

Can we say which analysis is the correct one for each of these data sets? By and large there is no best way to analyze the data. Each individual may have his or her favorite method, but in reality we are addressing a complex statistical issue for which there is no one correct way to analyze the data. Our problem is that different methods give different results. We cannot know which result to believe, but it is important to know that these differences occur.

Could the methods chosen to analyze the data influence the results? It is clear that the different models can give different results. None of the models fits the data well;

hence it is not possible to decide which model is best. There is no one correct way to analyze a data set. Hence an investigator has considerable freedom in the choice of his/her model. There are different ways to address the seasonal nature of the data; i.e., the patterns due to the fact that there are more health effects, such as deaths, in winter than in summer. An investigator can choose weather factors and the other pollutants he or she may place in a model. The investigator can decide whether to relate today's pollution with today's mortality, or yesterday's pollution with today's mortality or the average of the last 5 day's pollution with mortality. All of the above and more have been considered. Then there is the model construct itself; it could be linear, log-linear, or Poisson. Often an investigator may choose one method over another in order to ensure that all public health considerations are unearthened so that the public health can be protected at all costs. This has been a rationale for considering only one pollutant when others are equally likely to influence a health response; in their papers authors indicate that a specific variable was chosen because it maximizes the association between an air pollution variable and a health response. This may be "conservative", but it does not provide an accurate estimate of effect or association.

Usually we use a 5 percent level of significance in empirical research; that means that we accept that there is no effect when the chance of a positive result occurring is only one in twenty. However, the additional flexibility in model choice noted above alters the level of significance in statistical tests, making it more likely that the investigator will estimate a positive effect when none in fact occurs.

There may be other factors associated with the complicated data sets with which we work. The data are complex time series data, and we have little detailed understanding of these data sets. The models we apply are relatively simple models. We assume they are adequate for our data. In an effort to test this, Lipfert & Wyzga undertook some initial analyses to determine how these models performed with unrelated data sets; e.g., pollution variables for one city and unrelated health data for a distant city.

Our results are preliminary, but indicate some surprising significant relationships such as a statistically significant relationship between air pollution in one city and health impacts in a distant city. These provocative findings need to be resolved. It may be premature to suggest that they impact our evaluation of the current science, but it would be irresponsible not to investigate these findings further. I hope to clarify these results within the next 3 months.

Then there is the issue of pressures to emphasize positive studies. This is best described by the following quote from the July, 14, 1995 issue of *Science*, entitled, "Epidemiology Faces Its Limits." The article states "Authors and investigators are worried that there's a bias against negative studies," and that they will not be able to get them published in the better journals, if at all, says [Marcia] Angell [Executive Editor] of the *NEJM* [*New England Journal of Medicine*]. "And so they'll try very hard to convert what is essentially a negative study into a positive study by hanging on to very, very small risks and seizing on one positive aspect of a study that is by and large negative." Or, as one National Institute of Environmental Health Sciences Researcher puts it, asking for anonymity, "Investigators who find an effect get support, and investigators who don't find an effect don't get support."

Could PM be serving as an index for other pollution? If we regulated PM, would we achieve the health improvements we want? In other words can we disentangle the health effects of particulate matter from those of other pollutants and weather? To a limited extent we can, but we are hampered by two issues. All pollutants may be associated with health effects. Second, most urban pollutants are present at the same time. In addition, weather conditions can cause many pollutants to concentrate in an area at the same time, including those pollutants that are not measured. In fact weather conditions are often correlated with pollution as well.

Hence it is difficult to disentangle any effects of various pollutants and to indicate which pollutant may be associated with a given health effect. The Health Effects Institute and the Moolgavkar and Luebeck quotes above address this problem. In addition, in a paper Lipfert and Wyzga published in the *Journal of the Air and Waste Management Association*, we examined many published studies that had looked at the relationship between daily mortality and various pollutants. We found that if a study had chosen to focus upon sulfur dioxide or nitrogen dioxide instead of particulate matter, that study found similar effects on daily mortality as did those studies that focused upon particulate matter. A focus upon carbon monoxide indicated somewhat larger effects than particulate matter, and a focus upon ozone gave somewhat smaller effects. Given the high correlation between the various air pollutants, an obvious conclusion is that if an investigator had elected to study another pollutant instead of particulate air pollution, he/she might well have concluded that the other pollutant was the pollutant of concern.

Disentangling the various air pollutants is complicated because of statistical considerations. Lipfert and Wyzga have shown, and it is now widely accepted, that until one has an understanding of how well the measured pollution data represent the levels to which people are actually exposed, it is not possible to separate out the effects associated with various pollutants. The EPA Criteria document states, "Measurement error in pollutants or other covariates may also bias the results, . . . and the most poorly measured exposure covariate is usually the one that is driven toward no effect." Measurement error is caused by the fact that the amount of pollution measured by the monitor is not the same as that to which a person is exposed. This could be caused by inaccuracies in the instrument. It could be due to the fact that the monitor is not located in the same area of a city as an impacted individual, or it could be due to the fact that people spend most of their time indoors where pollution exposures may be very different from what is measured at a monitor.

Is there any relationship between the concentration of particulate matter in the air people actually breathe with the levels used in air pollution health studies? We know very little about what pollution levels people are actually exposed to; we know even less about how the actual exposures of people to particulate matter relate to the levels measured at outdoor monitors, which can be very distant from people's homes. Available data show no consistent relationship between the levels of particulate matter people actually breathe and the levels measured at outdoor monitors. This is also true when we ask whether personal exposure data track outdoor levels over time. In addressing this issue in its Criteria Document, EPA depends upon a study of seven elderly Japanese living in non-smoking, non-carpeted, "typical", Japanese homes in Japan. For this group, there was a good relationship between personal exposures and ambient measures of PM_{10} . The relevancy of this data set to Americans is, however, unclear. Other studies do not demonstrate as good a relationship between the air actually breathed and that measured at the monitors. A study in Phillipsburg, NJ looked at the relationship between personal (actual) exposures to PM_{10} and outdoor measures for 14 individuals. For the group as a whole, the personal exposures tended to increase with outdoor levels, but the results are not consistent across individuals. For some people a reduction in outdoor levels in PM_{10} would have no effect on the PM_{10} levels where people breathe. A study in Azusa, California compared the actual exposures and outdoor levels of ten people to $PM_{2.5}$ and PM_{10} for periods of 7 days. The results were not consistent. For half of these people, the actual exposures to $PM_{2.5}$ decreased when outdoor levels of $PM_{2.5}$ increased. No individual showed a striking positive relationship between personal exposures and outdoor levels.

Some studies have looked at people who might be more susceptible to air pollution. A group at the Gage Research Institute at the University of Toronto studied 21 asthmatics for both winter and summer periods for a total of about 20 days each. A correlation co-efficient of 1.0 would mean perfect concordance; a correlation co-efficient of 0.0 would indicate absolutely no association between the two. The average correlation coefficient across subject between actual exposures to $PM_{2.1}$ and measured outdoor levels was 0.11; (i.e., outdoor measures would explain about 1 percent of the variation in personal exposures.) This result suggests that changes in the outdoor levels of fine particulate matter ($PM_{2.1}$) would have negligible impact on the asthmatics' actual exposures. EPRI sponsored a study of asthmatics in Uniontown, PA. Our contractors from the Harvard School of Public Health measured the personal exposures and ambient levels of sulfates, a component of particulate matter, and found good agreement between personal exposure and outdoor levels. Unfortunately this study did not consider particulate matter as a whole.

We are currently supporting a study at Harvard School of Public Health of people with chronic obstructive pulmonary disease (COPD). We hope to understand the relationship between actual exposures of particulate matter (both PM_{10} and $PM_{2.5}$) and outdoor levels. The first part of the study was undertaken in Nashville and showed absolutely no relationship between these two measures for the ten people studied. We are currently repeating that study in Boston.

Why do actual exposures differ from levels measured at monitors? First of all, people spend little time in the vicinity of the monitor, which may not be in a very representative location. If an individual lives in the suburbs, and the monitor is in the center of the city, the monitor may not provide a good indication of the pollution level to which the individual is exposed. Second people, especially susceptible individuals, spend considerable time indoors, where some particulate matter may not be able to penetrate and where other sources besides outdoor air pollution can have considerable influence on a person's actual exposure to particulate matter. Sources of indoor particulate matter include passive cigarette smoke, vacuuming, dusting, pet dander, fireplaces and woodstoves, hairsprays, etc., etc. For this reason personal

exposures to particulate matter are often higher than outdoor levels because when we move, we generate a cloud of fine particulate matter around us, not too unlike that generated by the PigPen character in the Peanuts comic strip.

Is there any biological explanation for the results we see from these models? In its proposed decision to promulgate particulate matter standards, EPA states, "it is generally recognized that an understanding of biological mechanisms that could explain the reported associations has not yet emerged."

Is there any reason to believe that $PM_{2.5}$ is of greater health concern than PM_{10} ? There is no health evidence that $PM_{2.5}$ presents a greater concern than PM_{10} . In a recently published paper Lipfert and Wyzga reviewed 30 published papers (all that they could find as of that date) that examined the association between mortality and particulate air pollution. Some of these studies used PM_{10} as a measure of particulate air pollution; others used $PM_{2.5}$. We compared the results of the studies that used PM_{10} to those that used $PM_{2.5}$. The differences in estimated effects between the two particulate measures was small; if anything, the literature suggested greater effects were associated with PM_{10} .

There are a few studies that consider both PM_{10} and $PM_{2.5}$. If we consider the estimated effects of PM_{10} and $PM_{2.5}$ in a head-to-head comparison in these studies, we find little difference between the two indices. Where there is a difference, the estimated health effects of PM_{10} appear to be greater. For example, in Table 13-5 of EPA's Criteria document, EPA summarizes the results of the Harvard 6-City Study. The table presents the estimated changes in relative risk for increased chronic mortality in adults. The higher the number, the greater the estimate of increased risk. For PM_{10} or PM_{15} , it is 1.42; for $PM_{2.5}$, it is 1.31. Lipfert and Wyzga compared the PM_{10} and $PM_{2.5}$ results for all existing studies and found the estimated health effects of $PM_{2.5}$ to be less than or equal to the estimated effects of PM_{10} .

Why then does the EPA say that there is need for a $PM_{2.5}$ standard to protect public health? The basis for this argument is a paper based upon the Harvard 6-city study. That paper estimates the association between daily mortality and $PM_{2.5}$, PM_{10} , and the difference between PM_{10} and $PM_{2.5}$. EPA refers to the latter as the "coarse fraction". That study finds the strongest association between daily mortality and $PM_{2.5}$ and the weakest association between daily mortality and the "coarse fraction". In our opinion the analysis is flawed, however, because of the measurement error issue. In a paper recently accepted by the *Journal of the Air and Waste Management Association*, Lipfert and Wyzga show that the comparisons between $PM_{2.5}$ and the "coarse fraction" are inappropriate without any correction for the difference in measurement error. There are at least two types of measurement error present in the data collected. First of all, an earlier paper by the Harvard investigators noted that the device used created inaccuracies averaging 43 percent for the "coarse fraction". Second since $PM_{2.5}$ is more spatially uniform than is the "coarse fraction", the readings from a single monitor in a large geographic region (up to nine counties) will be much more representative for $PM_{2.5}$ than for the "coarse fraction." These two factors will bias downward the estimated impact of the coarse fraction. Our conclusion in this paper is: "In the specific study (Schwartz et. al, 1996) that we considered in detail, which employed a single monitor in each of six large metropolitan areas, we conclude that virtually nothing can be inferred about the true causal nature of daily mortality, the actual responses to these agents, or the shapes of the true response functions. Given the strong bias in favor of $PM_{2.5}$ resulting from lower instrument errors, less spatial variability, the treatment of missing data, and the near significance of coarse particles in spite of these handicaps, the most prudent conclusion from this study would have been that there is no apparent significant difference in mortality associations by particle size."

How accurately can we measure $PM_{2.5}$? A new standard, such as $PM_{2.5}$, requires defining the substance, $PM_{2.5}$, to be controlled. This is defined by the levels measured through an official reference method. For $PM_{2.5}$ this method is prescribed along with the proposed standard. Field testing of the reference method began late last fall. We too have been testing a suite of methods at the sites selected by EPA and/or State agencies. Our suite includes samplers that work on the same principle as the reference method. Test results are being analyzed by several groups; neither EPA nor our results have been published yet.

Our initial results indicate that in some cities the reference method would not capture a substantial portion of the fine particulate constituents, especially those that are likely to evaporate during the measurement process. These results are consistent with theoretical expectation. Therefore, we predict that the reference method is likely to provide incorrect and incomplete information from the standpoint of characterizing and managing any potentially harmful constituents of particles. Instead promising newer technologies ought to be considered.

SCIENTIFIC ISSUES FOR THE ANNUAL STANDARD

How strong is the evidence for that standard? The studies and issues I have discussed previously relate both to the daily and annual standards. Evidence to support changes in the annual standards come from a different type of study. Differences in the health of various communities are compared with differences in the air quality for these communities. Attempts are made to adjust for other factors (e.g., demographic or socio-economic factors) that may explain the health differences among communities. It is important that all potentially relevant factors be included in the analyses. This is particularly true for factors which vary regionally as does air pollution. These factors include regional differences in diet, lifestyle, and climate. Omitting such a factor from statistical analysis can shift the blame onto air pollution. These factors are referred to as confounding factors.

These studies have improved recently with the study of defined cohorts for which we have some individual characteristics, such as smoking history. The ability of these studies to control for non-air pollution factors is however, limited by the information collected. EPA cites two of these studies as providing support for their proposed annual standard for $PM_{2.5}$.

The first study was based on differences in cohort survival rates among the cities studied in the Harvard Six Cities study. EPRI was a funder of this study. This study is confounded by the failure to account for known lifestyle differences across the six cities. For example, EPRI-supported research has shown that differences in the fraction of the elderly population with sedentary lifestyles in each area can account for most of the differences in mortality among the study cities; moreover, the predicted effect of this lifestyle factor matches almost perfectly the relationship estimated in an independent California study by Breslow and Enstrom.

The second study also did not consider lifestyle factors; in addition, this study only evaluated mortality relationships with respect to sulfate and fine particles and did not test whether similar results might have been found for any other pollutants.

Neither of these studies considered the fact that the evaluation of chronic health effects must consider the typically long latency periods of such diseases and the air pollution histories of the cities being studied. Typically, the dirtiest cities have already improved greatly; hence chronic health effects could be due to the past dirty air, which initiated the process, the end result of which we see today.

CONCLUSIONS

Would the changes in the proposed particulate standards lead to improvements in public health? No one knows. The results of positive statistical studies must be balanced by the following issues:

(1) not all studies find a significant positive association between particulate matter and health;

(2) re-analyses of existing studies, by a wide range of scientists, do not support the conclusions of the original studies that there is a significant association between particulate matter and health;

(3) the choice of method to analyze data can influence the results;

(4) it is very difficult and often impossible to determine which specific pollutant may be related to health consequences; is it particulate air pollution or some other factor;

(5) there is an inconsistent relationship between the particulate levels in the air we actually breathe and that measured at monitors;

(6) we have no biological explanation for the results of the statistical models;

(7) if there is an association between particulate air pollution and health, there is no health information available that suggests greater health effects associated with $PM_{2.5}$ than with PM_{10} ; and

(8) to understand any health effects and to manage $PM_{2.5}$ concentrations, we need a more accurate definition of $PM_{2.5}$ than that of the proposed Federal reference method.

It is clear that we are dealing with a very complicated situation; the findings to date raise the specter of an important public health issue, yet there remain many unanswered questions before we can confidently conclude that these effects are real and we know how to improve the public health. We clearly need to work together if we are to resolve these questions. We need to pool our resources, share our knowledge and data to resolve these questions. It is fortunate that we as a society have already committed to reducing air pollution and pollution levels are in decline.

Let's continue to work together.

RESPONSES OF DR. WYZGA TO ADDITIONAL QUESTIONS FROM SENATOR INHOFE

Question 1. EPA has emphasized studies that support their proposal; are there either old or new studies that come to the opposite conclusion?

Response. There are many studies that do not demonstrate a consistent statistically significant association between air pollution and health. I cited several such studies in my statement, such as the studies of Styer et al. of Salt Lake City; Morris of Manchester, England; Roth of Prague, the Czech Republic; Burnett et al. of ten Canadian cities; and Abbey et al. of California. Reanalyses of existing studies also raise questions about the unambiguous association between health response and exposure to particulate pollution. These studies include Davis et al. of Birmingham, AL; Roth and Li of Birmingham, AL; Health Effects Institute of Philadelphia; Moolgavkar et al. of Philadelphia and of Steubenville, Ohio; and an EPRI reanalysis of Detroit.

In addition, there are several recent studies that come to a similar conclusion: Bacharova et al. of Bratislava, the Slovak Republic; Ballester et al. of Valencia, Spain; Ponce de Leon et al., of London; Schouten et al. of ten Dutch cities; and Wojtyniak et al. of four Polish cities.

There are two important factors to consider in this context. First of all, many negative studies don't get published. Journals are less likely to publish negative results than positive studies; hence there may be several studies with negative findings that have not been published, and we are therefore not aware of them.

The second point is one that I made in my statement. In every case where the data from a positive study have been re-analyzed, the re-analysis does not support an unambiguous statistically significant association between health and particulate matter. This is of concern because several key data sets are not available for re-analysis; hence it is unclear whether the results from these studies would remain the same if alternative, yet equally valid, statistical methods were applied to them.

Question 2. You mentioned the finding of statistical associations that clearly make no sense, that draw on similar techniques and some of the data used in EPA's studies; can you elaborate?

Response. The most common type of study considered by EPA is one in which daily levels of a health index, such as hospital admissions or deaths, are related to daily levels in particulate air pollution, after adjusting for other factors such as day of week, weather, time of year, or other pollutants. In the past Fred Lipfert of Brookhaven National Laboratory and I have examined many such data sets. We decided to look at relationships between pollution in one city and health indices in distant areas to see whether or not the methods used would provide similar results. One would not expect any association between these two presumably unrelated data sets; an association could occur only because of chance or because there of an artifact in the methods used to analyze such data sets. If the association occurs over several data sets, chance is not the likely explanation; rather we must conclude that there are serious concerns about the methods we are using to analyze the data.

We have related the following data sets and found statistically significant associations between:

- daily deaths in Santa Clara County (San Jose, CA) and daily air pollution (ozone) in Philadelphia;
- daily hospital admissions in Toronto and daily particulate levels in Philadelphia;
- daily deaths in the U.S. and daily particulate levels in Philadelphia;
- the number of daily births in the U.S. and daily Philadelphia particulate levels.

We tried to relate daily Philadelphia particulate levels to random numbers, such as lottery results, but we could not find any unexpected associations. This result suggests that there may be some inherent property of the time series data sets that is not properly considered in the analyses to date. We are investigating this issue at present with additional statistical experts, who specialize in analyzing data sets such as these.

We have not yet analyzed the relationship between demographic indices and particulate levels for cities other than Philadelphia.

This result merits immediate resolution because if the methods used to date are shown to introduce spurious associations between daily particulate levels and daily health indices, then the many studies cited by EPA and others are meaningless.

Question 3. Have you studied what happens on the days before and after peak air pollution episodes? Do your models account for the net effects?

Response. During the severe pollution episodes before 1965 in London and elsewhere, it was clear from looking at the data that mortality increased shortly after these episodes. See my answer to your fourth question. When we look at the data

plots, however, for the studies undertaken today at contemporary air quality levels, no such relationship is apparent. Pollution peaks are rarely followed by visible increases in any health index. If pollution were an important culprit, we would expect to see some signal in the health data. We do not. The model results appear to be influenced more by the temperate changes in pollution, an issue which also raises the possibility of some artifact being present in the methodology.

We have on occasion looked at the relationship between deaths on 1 day and pollution on subsequent days (i.e., the deaths precede the pollution), and we find some significant associations although this is not an issue that we nor anyone else, as far we know, have examined rigorously.

We have examined the net effects of pollution on mortality over several days in Philadelphia. In models where we can find an effect of particulate air pollution, we find that the net effect is zero after several days.

Question 4. How do the present peak periods of air pollution compare with those experiences in London during the 1950's and 1960's? Do we see the same kinds of health responses?

Response. Air pollution levels during the London episodes of the 1950's and 1960's were much higher, as much as a factor of ten higher, than episodes seen in the contemporary U.S.. We have dramatically decreased our pollution levels in the past thirty years, and this is true for fine particles as well as for larger particles. One speaker at the hearing gave the impression that polluters choose to control the larger particles selectively because their higher masses give a "bigger bang for the buck". The big gains in control of particulates have come from controlling combustion and manufacturing sources involving fine particles, by switching to cleaner fuels and installing particulate collectors. In recent decades, fine particles have been reduced by about 6 percent per year in New York, Philadelphia, St. Louis and Steubenville, Ohio, and we have every reason to believe that this trend will continue in response to clean air regulations already in force. Larger particles associated with road dust, agricultural sources, etc., are harder to control; hence further reductions of these particles may be more problematic.

In London, health responses to high pollution levels were obvious from looking at the data; this is not the case with recent studies. See answer to question 3. A curious finding, however, is that when the same models are applied to the London data during the high episode period and to contemporary data sets when pollution levels are much lower, we see similar results; i.e., the relative risks of air pollution has not changed despite the fact that pollution levels have declined dramatically. This result is difficult to explain. It could be due to the fact that we're controlling the wrong pollutants; it could be due to artifacts in the models and methods (See my answer to your second question.); or it could be that we respond to relative changes in the level of pollution rather than to absolute pollution levels. Any of these explanations would have significant implications on how we regulate and control air pollution.

ADDENDUM

I have one additional comment to make about an issue that was raised at the hearing. The recent experiment of John Godleski was mentioned. In these experiments, Dr. Godleski exposed compromised rats to Boston air in which particulates were concentrated by a fact of thirty for 6 hours a day for 3 days. Concentrations reached about 300 $\mu\text{g}/\text{m}^3$. The rats had previously been exposed to very high levels of sulfur dioxide to induce bronchitis-like conditions. After 3 days of exposure a significant fraction of the rats died. At the hearing, the statement was made that the average concentration of particulate exposure was 100 $\mu\text{g}/\text{m}^3$, a concentration on occasion found in U.S. cities. I believe that this statement is misleading. Rats were exposed at about 300 $\mu\text{g}/\text{m}^3$ for 6 hours, which could result in a 24-hour average concentration less than 100 $\mu\text{g}/\text{m}^3$, but we have no reason to average the exposure. Averaging the exposure without justification is equivalent to saying that standing 6 hours in a pool of water 10 feet deep is the same as standing in a pool of water 3 feet deep for 24 hours.

The experiments of Dr. Godleski are important and need to be resolved and understood, but they should not be misinterpreted.

STATEMENT OF JOHN CAHILL, ACTING COMMISSIONER, NEW YORK STATE
DEPARTMENT OF ENVIRONMENTAL CONSERVATION

Good Morning. My name is John Cahill, and I am Acting Commissioner of the New York State Department of Environmental Conservation. I appreciate this op-

portunity to present New York's perspective on the proposed amendments to the National Ambient Air Quality Standards for ozone and particulate matter.

As you are aware, Section 7409 of the Federal Clean Air Act requires that the U.S. Environmental Protection Agency establish National Ambient Air Quality Standards for criteria pollutants which "are requisite to protect the public health," and review these standards on 5-year intervals. Based on such a review, EPA has now proposed 4 revisions to the standards for both ozone and particulate matter. While we are encouraged with the efforts of EPA to meet these requirements of the Clean Air Act, and support efforts to ensure that the air quality standards are protective of the public health, we have several comments to make regarding EPA's proposed revisions.

In its 1991 report "Rethinking the Ozone Problem in Urban and Regional Air Pollution," the National Research Council identified several shortcomings in EPA's existing strategy to reduce concentrations of tropospheric ozone. In its report, which was mandated by the Clean Air Act, the Council suggested that the existing monitoring tends to measure transient "spikes" in ozone concentrations rather than baseline or average levels, and is overly sensitive to weather fluctuations. Both of the problems, the report concluded, could be traced to the fact that the existing ozone standard looked at concentrations on a peak 1-hour basis. We are therefore supportive of EPA's proposal to amend the ozone standard to an 8-hour interval.

Over the years, New York has had some success in meeting the existing ozone standard of 0.12 parts per million. Most of upstate New York, which had been in non-attainment with the standard, has recently experienced several years of "clean data." Even the New York City metropolitan area has shown a marked reduction in ozone levels. The region exceeded the standard only two times during the 1996 ozone season, compared to 38 times in 1980. While we will support any standard that is based on strong scientific evidence, we are concerned about the impact a revision to the ozone standard will have on New York's efforts to meet Federal air quality goals, especially without dramatic improvements in the quality of air entering the State.

For instance a revision of the standard to 0.07 ppm, the more stringent scenario in the EPA proposal, could cause most of the upstate region to be once again designated as non-attainment. There is evidence that baseline levels of ozone could reach as high as 0.06 ppm, therefore making a standard of 0.07 ppm virtually impossible to attain. As previously stated, we support setting the standard at a level which is protective of the public health, but setting it so low that it could conceivably never be attained, even under the best of circumstances, would benefit no one. Literally billions of dollars would be spent chasing an unattainable goal.

It is difficult to ascertain just how the upstate region of New York would fare if the standard were set at a level of 0.08 ppm. Available data from the last 3 years indicate that much of upstate New York is currently hovering around the 0.08 level. This makes it vital that EPA use real-world monitoring data for the coming years, rather than modeled predictions based on previous data, when making its attainment designations. EPA should also require affected States to install monitoring networks with sufficient density to provide robust data and high confidence in the designations it does make. In this manner, improvements made in the upstate region in the next 3 years will be included when making an attainment determination. We further support EPA's proposal to require measurements to be taken to two decimal points (0.08) rather than three (0.080).

Another concern relating to the proposed amendments involves modifications to the existing designation levels that would be needed as a result. Currently, the five levels of ozone non-attainment, ranging from marginal to extreme, and the associated control strategies are set forth in the Clean Air Act. Any changes made to the existing standard will require corresponding modifications to these designations as well and, therefore, the control strategies a given area would have to implement. It is our understanding that these amendments would be made by EPA in a rule-making. We therefore feel it is vital that there be sufficient opportunity for the States and other interested parties to participate in drafting such regulations, and to review and comment on any future changes to the non-attainment designations before they are implemented.

While there may be some uncertainty regarding how the proposed amendments to the ozone standards will affect upstate New York, it is likely that certain segments of the Midwest would be reclassified as non-attainment if the new standards are implemented. New York State has repeatedly expressed concern that it will never be able to meet even the existing ozone standard so long as the air entering the State at its western and southern boundaries already exceeds that standard. As a member of the Ozone Transport Commission, New York has enacted several control measures beyond those required by the Federal Clean Air Act in an effort to

attain the ozone standard. We have also actively participated in the Ozone Transport Assessment Group, consisting of the 37 States east of the Rocky Mountains, in hopes of achieving significant reductions in the long-range transport of ozone and its precursors. Regardless of the final outcome of the proposed amendments to the ozone and particulate matter standards, it is crucial to New York's attainment strategy that the large sources of ozone precursors located in the Midwest and Southeast be required to install the same level of controls currently required in the Northeast. In this manner, the air quality of the entire region will improve, and the Northeast will be able to compete on equal footing with the Midwest as the electric generation industry is deregulated. We further support EPA's position that the negotiations and rulemakings regarding long-range transport of ozone precursors now underway should not be postponed as the revisions to the air quality standards are considered.

As with the ozone standard, we are concerned about the environmental and public health impacts of long-range transport of fine particulates. In a recent report, the American Lung Association estimated that inhalation of particulates is responsible for some 60,000 premature deaths in America every year. Epidemiological evidence suggests that fine particulates pose an immediate risk to the health and well being of our citizens. The same contaminants that are largely responsible for fine particulates are also significant contributors to both ozone formation and the acidic deposition that continues to plague the forests and water bodies of the Northeast. Reductions in emissions in the OTAG region that lead to these particulates will therefore pay off fourfold, resulting in decreases in acidic deposition and ozone as well as the direct reductions in particulate matter, which in turn will help improve visibility throughout the region.

As with the proposed changes to the ozone standard, it is important that EPA base any redesignation for the particulate matter standards on observed, real-world data rather than on computer modeling. EPA will also soon need to propose and finalize specifications for the equipment used to monitor fine particulates. From our recent experience in designing and installing monitors in New York City, it is clear that there will be considerable additional expense associated with the monitoring network needed to determine compliance with the new standards. As Federal funding for compliance with the requirements of the Clean Air Act continues to dwindle, EPA must be cognizant of the substantial increase in resources that will be needed to meet the monitoring requirements of both the ozone and particulate standards.

In conclusion, New York fully supports the efforts of EPA to set new standards for ozone and particulates, provided that they have a scientific basis and are attainable. We feel that an 8-hour ozone standard is preferable to a current 1-hour standard, both to reduce the impact of weather fluctuations, and to provide an accurate assessment of the true effectiveness of control strategies by measuring average ozone levels rather than worst case, transient events. We also feel that EPA and Congress should be cognizant of the costs these new standards will impose on the States when considering funding levels for grants under Section 105 of the Act. The Department will be submitting more detailed comments before the close of the public comment period. Thank you again for providing me with this opportunity to present our viewpoints on this matter.

STATEMENT OF THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
(ASTHO)

The Association of State and Territorial Health Officials (ASTHO) is pleased to present its views on the U.S. Environmental Protection Agency's (EPA's) proposed rules regarding the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) and ozone, the Agency's interim implementation policy, and its proposed surveillance methods for particulates. 61 Federal Register 65637, 65715, 65751 and 65780 (December 13, 1996). ASTHO represents the public health agencies of each of the U.S. States and territories and its members are the chief executive officers of the health department of every U.S. State, territory and possession. ASTHO engages in a wide range of legislative, scientific, educational and programmatic activities to improve public health. Because human health effects are the foundation of the proposed revisions to the NAAQS, ASTHO and its members are vitally concerned that any proposed revisions to the NAAQS have a sound scientific foundation and promote a beneficial national public health policy.

SUMMARY AND RECOMMENDATIONS

ASTHO believes that EPA's proposed NAAQS for fine particulates and ozone will result in far fewer cases of adverse respiratory effects, but in the absence of demonstrated thresholds for adverse health effects, they will not fully protect the public.

Exposure to 20 to 30 micrograms per cubic meter of fine particulates have shown adverse health effects, and argue for the NAAQS to be set lower than that level. Adverse health effects from ozone are also reported at 0.08 ppm in prolonged exposure with moderate exertion, leaving little apparent “adequate margin of safety” in any proposed standard.

Since the standards will not fully protect the public, the Agency should develop a system to warn the public about high levels of particulates in the atmosphere, similar to warnings now given about ozone levels. Such warnings about both particulates and ozone would allow individuals to take measures to protect themselves against these potential health hazards.

EPA reviewed 86 studies of human health and particulate matter and 185 studies of ozone and human health as the basis for the proposed standards. The Agency has presented a wealth of evidence that ozone produces human health effects at the current NAAQS, and sufficient evidence that particulate matter, including fine particulates, may present a danger to public health. Thus, ASTHO believes that the Agency’s decision to move forward with new standards is justified on public health grounds.

ASTHO believes that the proposed PM_{2.5} standard should supplement, not replace, the existing PM₁₀ standard. Coarse particles are also likely to cause adverse health effects, and people should be as protected as possible against exposure to them as well.

EPA’s proposed 24 hour average measurement standard for particulates ignores the highest daily exposures, and could result in an additional week or so each year of daily exceedences without violating the standard. Sensitive populations could needlessly suffer additional episodes of illness or death when exposed to these short term, high particle levels.

PARTICULATE MATTER

EPA reviewed 86 health studies of human health and particulate matter as part of the foundation for the proposed revision to the NAAQS. ASTHO believes that the Agency’s effort in reviewing the scientific data has been thorough, and that the scientific evidence is sufficient to generate concern that particulate matter, including fine particulates, may presently be a danger to public health. While some may have criticized the relative lack of data regarding exposure to fine particulates, the uncertainties regarding the composition of particulate matter, or the confounding influence of sulfur oxides and other pollutants, the existing data supports the Agency’s proposed action. Additional studies that EPA did not explicitly cite, and which estimated the concentration of fine particles through impaired visibility corrected for humidity, also support the Agency’s action to regulate fine particles.

Consequently, ASTHO agrees that EPA should regulate PM_{2.5} as well as the present PM₁₀. The Agency stated in its summary that studies consistently find adverse health effects at exposure concentrations between 20 and 30 micrograms per cubic meter, and find mortality effects above 30 micrograms per cubic meter. Such findings argue for NAAQS set lower than levels at which effects become apparent if the standards are to protect human health with an adequate margin of safety.

Moreover, ASTHO believes that the PM_{2.5} standard should supplement, not replace, the existing standards for PM₁₀. Coarse particles are likely to cause adverse effects as well as fine particles, and full implementation of a new NAAQS may take a decade or more. The coarse particles are more common in the western states than in the east, and eliminating the present standard would leave people living in the west relatively less protected. Even if the existing standard were eventually phased out, people should not be left with less protection during any period of transition.

EPA has also proposed to rescind the current 24 hour PM₁₀ standard or to retain it at its current 150 micrograms per cubic meter, a level that EPA openly acknowledges would not protect public health. Virtually all recent studies of mortality and morbidity have used PM₁₀ as the principal, if not the only, measurement of particulate matter. While PM₁₀ may be a proxy for fine particles, coarse particles may also be important in determining health outcomes. The current state of the science cannot distinguish effectively between the impacts of fine and coarse particles in the vast majority of epidemiological studies of PM₁₀, especially where health outcomes affect the airways. Significant quantities of both fine and coarse particles can easily penetrate the bronchial tree and deposit in the airways. Several studies in which the coarse fraction either dominated PM mass or in which PM_{2.5} was measured concurrently with PM₁₀ or PM₁₅, found that coarse particles were associated with adverse lower respiratory outcomes.

Epidemiological data indicate that exposures to low concentrations of ambient PM₁₀ have been linked consistently with airway related diseases. These studies do

not show clearly, however, whether the relationship is stronger for coarse or fine particles, or whether the associations are roughly equal. Public health efforts, then, should continue to focus on reducing exposure to a pollutant indicator, PM_{10} , that is linked to airway conditions such as asthma and bronchitis. Thus, ASTHO believes that a PM_{10} standard should be retained in addition to putting the new $PM_{2.5}$ standard in place. The weight of scientific evidence, however, supports lowering the current 24 hour PM_{10} standard to protect public health.

ASTHO encourages EPA and other Federal agencies to continue to pursue and sponsor additional research on the public health implications of ambient $PM_{2.5}$. Such research should include epidemiological investigations of potentially susceptible subpopulations, the relative strength of human health effects due to exposure to specific particle sizes, indoor penetration of both fine and coarse particles, biological mechanisms of action, and health effects due to PM composition.

ASTHO is concerned that the Agency's proposed criteria for attaining standard for fine particulates may not protect public health sufficiently. EPA proposes that 24 hour attainment would be measured by taking the 98th percentile of daily averages over 3 years. Such a standard, of course, ignores the highest daily averages, and could mean an additional week or so of daily exceedences without being in violation of the standard. Sensitive populations could suffer additional illness or death when exposed to high particle levels during these allowed short term excursions above the standard. The Agency should remember that epidemiological studies show that health effects are associated with short duration, high concentration episodes.

In addition, measured particle concentrations would be averaged over several monitors in the area being monitored. Depending where the monitors are placed, such an averaging protocol would leave some people overexposed. For instance, if one monitor is placed in an area that routinely has high particulate concentrations and others are placed in more pristine areas, people living in the area of high concentration would be left less protected than others.

The topography of western states places this area at greater health risk under the monitoring protocol. The measurement protocol would work best in a terrain that is relatively flat and that facilitates atmospheric mixing. The west, however, is often characterized by deep mountain valleys and temperature inversions that prevent such mixing. Tall buildings in urban areas can create "urban canyons" which inhibit air mixing as well. The result can be radically different concentrations in areas that are relatively close together. Average measurements of individual exposures under these circumstances could easily be misleading.

While ASTHO agrees that EPA should try to limit public exposure to fine particulates, we also recognize that because no threshold exposure has been identified, some individuals will remain unprotected by EPA's NAAQS for fine particulates.

For this reason, ASTHO believes that the Agency should develop a system to warn people about ambient particulate levels so that sensitive individuals can take measures to protect themselves. Such a system would require daily measurements to acquire sufficient data to make predictions accurately, and could be modeled after the ozone reports routinely given in weather reports and forecasts.

In areas without PM monitoring, particulate concentrations could be modeled and predicted based on the visibility impairment each day in a defined geographic area. That visibility impairment would then need to be corrected for the humidity each day in that area. Such a modeling effort would require an advance over the present state-of-the-art, but ASTHO believes that such an effort, when successful, would act to protect public health. It would be similar to the turbidity criteria currently used to issue "boil water" alerts for drinking water.

OZONE

In its review of 185 studies, EPA has presented a wealth of evidence that human exposure to ozone produces adverse health effects at the current NAAQS. In fact, studies show that adverse effects occur during prolonged exposure to ozone along with moderate exertion at least down to the new proposed 0.08 ppm level. Consequently, little "adequate margin of safety" would seem to exist for acute effects at this, or any other, level that the Agency has proposed as a possible new standard. The 0.08 ppm proposed standard, if expressed as a long term annual average would, however, approximate estimated background exposure and would be virtually indistinguishable from background risk for chronic, but as yet unknown, human health effects.

The Agency should recognize publicly that any of the proposed new NAAQS for ozone will not completely protect the public from acute health effects because no threshold has been shown to exist. Many people will still be placed at health risk

no matter which NAAQS the Agency chooses, especially people with preexisting conditions that make them especially susceptible to respiratory effects.

ASTHO believes that EPA should act to ensure that the public is aware that it will not be completely protected from health effects related to ozone exposure with the adoption of new standards, and that susceptible individuals must continue to protect themselves from exposure to this substance.

CLEAN AIR ACT: OZONE AND PARTICULATE MATTER STANDARDS

WEDNESDAY, FEBRUARY 12, 1997

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, DC.

PROPOSED NEW FEDERAL STANDARDS FOR OZONE AND PARTICULATE MATTER

The committee met, pursuant to notice, at 9:30 a.m. in room 406, Senate Dirksen Building, Hon. John H. Chafee (chairman of the committee) presiding.

Present: Senators Chafee, Smith, Kempthorne, Inhofe, Thomas, Bond, Allard, Sessions, Baucus, Hutchinson, Lautenberg, Lieberman, Reid, Boxer, Warner, and Wyden.

OPENING STATEMENT OF HON. JOHN H. CHAFEE, U.S. SENATOR FROM THE STATE OF RHODE ISLAND

Senator CHAFEE. I want to welcome you all to the Environment and Public Works Committee, and we want to welcome Administrator Browner here today and those accompanying her.

This is the way we're going to do the opening statements. I will make an opening statement, then the ranking member, Senator Baucus, will make an opening statement, or be available for one, if he wishes, the chairman of the subcommittee and the ranking member of the subcommittee. But that's all we want to have for opening statements. If people want to include their statements in the record, obviously, that would be fine, and if they wish to give their opening statement during their questioning period, that's fine too. But we've got a lot to do today, and so that is the way we will proceed.

The purpose of our hearing is to review the national ambient air quality standards for ozone and particulate matter that EPA published last November. These are very complex and far-reaching proposals. After careful review, I am concerned that they may be too far-reaching.

Let me illustrate: it is possible to push too far and too fast. Consider the history of the Safe Drinking Water Act. I believe everyone now agrees that the 1986 Amendments to the Safe Drinking Water Act went too far. Many of us on this committee were here at that time. That legislation overloaded the States and community water systems regulated under the law.

The problems with the drinking water program were created by Congress, not by EPA. The 1986 drinking water bill was based on

the best of intentions. I am sure that if we reviewed the testimony at that time supporting the legislation—we were working on it from 1984, 1985 and 1986—you will see statements very similar to those you will hear today. Children are at risk of adverse health effects because they are exposed to toxic pollutants. We could avoid disease outbreaks and hospital costs by improving control technologies. A large number of Americans die prematurely each year because of contaminants that could be reduced.

The 1986 drinking water amendments responded to those public health concerns. Congress had the best of intentions, but we overloaded the system. As the 104th Congress opened, the Safe Drinking Water Act was cited in hearings all across the Capitol as the best example of what went wrong with the Federal Government.

With the hard work of Senator Kempthorne, Senator Baucus, Senator Reid, and all the members of this committee and the support of EPA, we reformed that law last year, as Administrator Browner remembers. We got rid of the overload. It is back on the right course now, but it was an experience, I believe, we should keep in mind. Even in the name of public health, it is possible to press too far too fast.

Now, I would like to contrast that with another statute that we passed, the ban on chlorofluorocarbons. Destruction of the ozone layer is about as serious an environmental problem as you can imagine. It is a worldwide threat that will take a century or more to correct. I suppose there are some at the beginning when the first scientific papers were published in the early 1970's who thought we ought to ban all CFCs immediately, but we didn't take that course. Under the leadership, first, of Lee Thomas, Administrator Lee Thomas, and later of Administrator Bill Reilly, we took a more incremental approach.

We moved step by step, starting with a freeze, then we had a reduction. There was a tax to discourage use, and eventually we achieved a ban on all CFCs. At first we didn't address all of the ozone depleting chemicals, but the list grew as we went on. The control program advanced quickly but only as it was supported by good science and wide public support. In fact, many of the decisions made by the EPA along the way were immediately endorsed by scientists of chemical companies that manufacture the CFCs. People knew that improving the science was the key to getting rid of CFCs. Improving the science became a high priority. That is an experience to keep in mind, and I think it is well that we remember that. It is possible to make rapid progress in even the most difficult environmental problems with science serving as the foundation for public consensus.

Now, how do those experiences affect us today? I think it is appropriate to ask whether the proposed standards for ozone and particulate matter are the right measures or if they go too far, if they overload the Clean Air Act.

Frankly, there is reason to be worried about how the Clean Air Act is functioning. Although the EPA has done a good job on the acid rain and stratospheric protection provisions of the 1990 Amendments, the ozone non-attainment program has fallen far behind schedule, and these two new proposed standards, among the

very largest regulations ever issued by the EPA, would be piled on top.

Apparently, some are of the opinion that concerns about overloading the system cannot be considered when these standards are set. According to this view, we must wait for the implementation phase to determine whether we have gone too far. I hope that is not what the Clean Air Act says. If it is, I think we put the tremendous achievements of the Act in jeopardy. Surely, we can find a way to work together to address the important public health concerns that the newest science indicates might be caused by air pollution without providing fuel for another round of attacks on our environmental laws.

Now, we'll turn to Senator Baucus for his opening statement.

**OPENING STATEMENT OF HON. MAX BAUCUS, U.S. SENATOR
FROM THE STATE OF MONTANA**

Senator BAUCUS. Thank you, very much, Mr. Chairman.

First, I appreciate your statement here. I think it is important to remind us all of where we are in this process.

Last week the subcommittee heard testimony from scientists, and I think a fair summary of that statement from the scientists is that there is a significant problem with the ozone, and there is an agreed upon range within which the EPA should adopt a standard. The particulates—as I recall the testimony, it was agreed that there is a significant problem with particulates, but there is some dispute among the CASAC members as to exactly what that standard should be. In fact, the CASAC panel itself did not recommend a particular standard.

I think it is also important to remind ourselves, at least in this instance, that we are not considering any statutory changes to the Clean Air Act. Rather, we are here at the beginning of a fairly long process to help the Administration and the EPA determine what the proper ozone and particulate standards should be.

This is, again, the beginning of a very long process. The EPA has not yet proposed its final regulations. We don't even know what the final regulations are going to be, and I think it is important for us at the beginning of this process to keep an open mind and not rush to judgment as to whether the initial proposed standards are proper or not.

Later on this year, perhaps this summer, the EPA will issue its final regulation after listening to all the comments. Then there is a long process, which looks at the cost side of it, with the development of State implementation plans which decide how the standards should be achieved. By then, of course, we may see new technologies to alleviate the problems in implementing the standards.

I want to contrast this process with the Safe Drinking Water Act Amendments. The Safe Drinking Water Amendments in 1986 were passed, I think almost unanimously, by this Congress, and signed by President Reagan. But those were statutory changes. The law provided for new tight standards to protect drinking water in our country. It is true that in retrospect the statutory standards were a bit too tight, particularly for small systems, and they imposed monitoring requirements demanding expensive technology to have to then be implemented, and the Congress did look at the many

hearings and move to change the statutory provisions, as provided by the Safe Drinking Water Act.

Senator Kempthorne, myself and others worked very hard on that, and I compliment them. So the analogy of the Safe Drinking Water Act is really apt. Really we are talking here about advice and clearing the air, so to speak, on what the proper regulation ultimately should be. I urge all of us not to undermine the process and not to rush to judgment. We should ask open-minded questions about how the EPA arrived at this standard, how many people they think are going to be harmed without the standard and how that might change with the proposed new standard. There are still a lot of questions. I think it is unwise to rush to judgment and criticize a proposed standard before it is even promulgated. We don't even know what the standard is yet.

Thank you.

Senator CHAFEE. Thank you very much, Senator.

Senator Inhofe, who is the chairman of the subcommittee, and then when Senator Graham gets here, we'll hear his opening statement and that will end the opening statements.

**OPENING STATEMENT OF HON. JAMES M. INHOFE,
U.S. SENATOR FROM THE STATE OF OKLAHOMA**

Senator INHOFE. Thank you, Mr. Chairman.

I'll submit the longer statement for the record.

First, I want to say that everybody in this room—Administrator Browner, and Senator Thomas, all of us want clean air, we want safe air.

A week ago today, the clean air subcommittee held a hearing to hear from the scientific community on this issue. I don't think there is anyone up here at this table who would hold himself or herself out to be an expert in these areas so we have to rely on experts, and that was the reason for the Clean Air Scientific Advisory Committee to be written into the statutes, and the Administrator has to rely on them also.

So we had all these people, and if there was one overall theme that we learned last week at the hearing, it was that there is a lack of scientific consensus about the judgments made by the EPA in issuing the regulations.

In addition, some of the important points would include, and I'll name six real quickly.

More time is needed—and this is eight scientists that came to this conclusion—No. 1, more time is needed to conduct additional research; No. 2, the EPA's decision was based on a policy call, not a scientific consensus; No. 3, there is no obvious bright line separately a level at which ozone and PM become dangerous for health effects; No. 4, the PM studies were based on statistical association—and this is very significant because I think they all said there are no biological mechanisms here, and that is what you would be looking for in order to justify the promulgation of more stringent rules; No. 5, there is inconclusive evidence regarding the particulate matter size and the possible health effects; and, No. 6, different researchers are producing different inconsistent results from the research on particulate matter. We had that come up in this committee where other researchers came and refuted some of the

accusations that were made by some of the previous scientists, Dr. Schwartz.

The Washington Post said that no one succeeded in accomplishing what 15 senators and scientists purportedly set out to do yesterday, resolving the scientific questions behind the Federal Government's latest proposed clean air standards. The Washington Times scientists yesterday said the available research wasn't enough to determine whether the plan would do what it is intended to do, but they disagreed on the potential benefits.

In my State of Oklahoma, a statement appeared in the Daily Oklahoman; it said, "Senators can't find clean air in the haze." So I think later on, when we have more time, we can talk about some of the specific statements that were made by Dr. Wolff, who is the chairman of CASAC, and Dr. Lippmann, who serves on CASAC, and their job is, of course, to advise the EPA on the scientific issues.

Now, what I would like to do—I agree with Senator Baucus, who says we don't want to rush to judgment on this. There is too much yet that we need to determine, and I don't want to use a threat of a court order, as an excuse to go in and exercise bad policy. I am not a lawyer, but I've spent a lot of time looking at the imposition of legal mandates. My conclusion is that you don't have to change the current standard. The court order doesn't require a change unless scientific evidence is there, and also there is nothing magical about 5 years. We should find out, and do something or do nothing now, and find out 3 years from now. We have conducted the studies and talked about it a week ago today that there is nothing to keep us from going in at that point and being in full compliance with the court order.

So I look forward to hearing from you, Mr. Chairman.

Senator CHAFEE. Well, thank you very much, Senator Inhofe.

The ranking member of the Subcommittee is Senator Graham, and he is not here—

Senator BAUCUS. He'll be coming later.

Senator CHAFEE. All right, so we will proceed with Ms. Browner. We welcome you, Madam Administrator and look forward to your testimony.

Now, I notice—I think it is 27 pages long, isn't it?

Administrator BROWNER. I would like to submit for the record the 27-page length testimony, and, if I might, just provide a summary of that in my opening comments.

Senator CHAFEE. We greet that with applause.

STATEMENT OF CAROL M. BROWNER, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, DC.; ACCOMPANIED BY: MARY NICHOLS, ASSISTANT ADMINISTRATOR FOR AIR AND RADIATION AND ROBERT HUGGETT, ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT

Administrator BROWNER. Thank you, Mr. Chairman.

Mr. Chairman, Senator Baucus, members of the committee, good morning, and thank you for the opportunity to testify on the EPA's proposed revisions to the national ambient air quality standards for particulate matter and ozone, better known as soot and smog.

Appearing with me today will be EPA's assistant administrator for Air and Radiation, Mary Nichols, and our assistant administrator for Research and Development, Dr. Robert Huggett.

Mr. Chairman, let me begin by saluting both you and Senator Baucus for your long-standing and steadfast leadership on environmental issues. As you know, it was a spirit of bipartisanship that launched the Clean Air Act under President Richard Nixon more than a quarter century ago, and it was that same bipartisan spirit with this committee in the lead that resulted in the strengthening of the Act under President Bush in 1990.

Today, under President Clinton the commitment to clean air remains strong. Thanks to your leadership and to the success of the Clean Air Act many millions of Americans are breathing healthier air. Millions of our children are protected from the harmful effects of breathing polluted air. Make no mistake—the Clean Air Act has worked for America. It has helped protect the public health and it has done so without holding us back.

Since 1970 emissions of the six major air pollutants have dropped by 29 percent while the population has grown by 28 percent, and the Gross Domestic Product has nearly doubled, economic growth and cleaner air. Now that is a level of progress we can all be proud of, which brings us to today's question: where do we go from here? Do we rest on our laurels? Do we stand back? Do we say that because we are making progress there is no need to revisit our standards, no need to reassess them in light of new scientific findings, no need to ensure that they are adequate to protect the health of the American people?

Wisely, the Clean Air Act since its inception does not allow us to make that choice, to simply stand still. The Act contemplates the march of technology. It envisions that science will come up with better ways to understand the health effects of the air we breathe, and that the standards of the 1970's might not be right for the 21st century.

The Act includes language directing the EPA to review the public health standards for major air pollutants at least every 5 years in order to ensure that they reflect the best, the current science. It also lays out a specific procedure to obtain the best available current science, and, if needed, revise the standards.

This is to ensure that we never get to a point where the Government tells the American people their air is healthy to breath when in fact the scientific community knows it is not healthy.

As you know, the EPA is now under a court ordered deadline to fulfill this obligation, and to publish a final decision on revisions to the particulate matter standards by mid-July. One of the accomplishments of this proposal of which I am the most proud is the fact that for the first time we are simultaneously proposing air quality standards for more than one pollutant. We do this largely for the purpose of allowing State, local governments and industry to develop common sense, cost-effective strategies for meeting those standards and to provide the American public with the most accurate information about the quality of the air they breath.

In accordance with the law, the EPA has asked an independent panel of scientists and technical experts from academia, research institutes, public health organizations and industry to review our

work and the underlying health studies and to make recommendations. That panel, known as the Clean Air Scientific Advisory Committee, or CASAC, over a 4-year period conducted 11 meetings, all open to the public, a total of 124 hours of public discussion. Panel members reviewed thousands of pages of materials prepared by EPA and integrating the best available science. The EPA has held further public meetings at which hundreds of representatives from industry, State, local governments, organizations, as well as members of the public have offered their views.

I can safely say that this has been the most extensive scientific review and public outreach process ever conducted by the EPA for public health standards. Over the course of this process we looked at more than 5,000 scientific studies of the health effects of smog and soot.

Mr. Chairman, this stack of papers is the bibliography of more than—a list of more than 250 scientific studies covering more than 10 years of analysis focusing on the human health effects of polluted air. These are the ones that CASAC agreed should be the basis for a public health standard. Page after page, study after study, every single one of these studies in this bibliography was peer reviewed. It was published in a scientific journal before it was even considered by the EPA, before it was presented to CASAC, which then literally engaged in another peer review. This is literally peer review, of peer review, of peer review. There are included here 185 studies on ozone, 86 studies on particulate matter, literally study after study indicating that our current air standards are not adequately protecting the public's health and that they should be strengthened.

After a thorough review of this evidence, the conclusion of the independent panel is that the most recent scientific information provides sufficient evidence that serious health effects are occurring in children, the elderly and other sensitive populations at particulate matter in ozone concentrations at, and below, existing standards. Clearly, the science calls for action—action to protect millions of Americans and especially millions of our children from harmful air pollution.

In a most compelling way, the science leads us to the new stronger standards that EPA proposes for smog and soot. For smog we propose to change the standards from .12 parts per million of ozone measured over 1 hour to a standard of .08 parts per million measured over 8 hours. In effect, the .12 1-hour standard is roughly equivalent to .09 when measured over 8 hours. Thus, to provide the needed measure of public health protection that the science and the law calls for, we propose to change the concentration from .09 to .08.

As the chart to my left indicates, Mr. Chairman, this new ozone standard, if adopted, would protect nearly 50 million more Americans from the adverse health effects of smog—

Senator CHAFEE. Madam Administrator, when you refer to the chart, I wonder if you could have someone point to the significant—first of all, I find it hard to read that chart; and, second, if somebody could point to something significant that you are dealing with that pertains to your testimony, that would be helpful, at least it would be helpful for me.

Administrator BROWNER. I apologize. What the chart shows—to put it out as simply as we can—the first column are the numbers of people protected under the current standard, the .12, which is roughly equivalent to a .09 at 8 hours. The other column, the second column, shows you under the proposed standard, which we now invite public comment on, the number of people who would be protected.

Senator CHAFEE. That's the column to the right, way over to the right?

Administrator BROWNER. Way over to the right, exactly.

Senator BAUCUS. Could you read those so that everybody knows what the numbers are?

Senator BOXER. Could you tell us what the difference is in total of the number of people—more people that would be protected with the proposed standard because we can't see the numbers?

Administrator BROWNER. Oh, I apologize. It is—under the proposed .08 8-hours the protections speak to 122 million Americans, and what that is is a combination of the numbers that have been broken out—the number of children protected, which is 33 million—again, this is just on ozone; this is just on smog, not on the fine particles—the asthmatics protected, the people with respiratory diseases protected and then a total number of Americans who would be protected.

Senator BOXER. What is the difference from the current—

Administrator BROWNER. A difference of 48 million Americans.

Senator BOXER. Thank you.

Administrator BROWNER. If I might, Mr. Chairman, continue.

In setting the standards and proposing the standards, the law requires us to provide what is called an adequate margin of safety. Certainly, there is no more appropriate application of that requirement than to ensure that our children simply by playing outdoors are not doing irreversible damage to their health. I think it is important to remember that children are among the most vulnerable to polluted air. They breathe in 50 percent more air per pound of body weight than do adults. They're small; their bodies are different. They are growing, and they react differently to pollutants. Many children spend a great deal of time outdoors during the summer when ground level ozone is at its most severe.

For PM, for the particulate matter, we would maintain our current standard on the larger or coarser particles, and we would propose a new standard on smaller particles, those at or below 2.5 micrometers in diameter. That is what the current, best available science has determined is damaging to human health.

Again, the law requires us to provide an adequate margin of safety in protecting the public's health.

Now, hopefully, you can see this next chart. That is bigger.

Senator CHAFEE. That's progress. I would get your chart makers in the future to use the full chart.

Administrator BROWNER. When you strengthen the PM standard in the way that the EPA proposes, you can see this chart displays what happens. Each year 20,000 fewer premature deaths, 250,000 fewer cases of aggravated asthma, 250,000 fewer incidents of acute respiratory problems, and in children 60,000 fewer cases of bronchitis, 9,000 fewer hospital admissions. Taken together, these pro-

posed standards for smog and soot would increase the total number of Americans protected to 133,000 million, including 40 million children.

Mr. Chairman, let me just say—and I know you recognize this—it is a tough issue. It is certainly one of the toughest I have faced in my 4 years at the EPA, but I do believe that the American people want us to follow the law. It is a law that has served us well for 25 years. They want us to protect the public health and do so with the latest, best available science.

The best current, peer reviewed, fully debated scientific conclusions are that too many Americans are not being protected by the current standards for these pollutants. Based on all we have seen to date, we believe there is quite literally no other alternative but to propose to strengthen the public health standards.

That doesn't mean there is no role for the practicality of attaining these standards. There is such a role, and it is appropriate when we move to the implementation phase of the law. We are now in the public health phase of the Clean Air Act.

In that case, as we look at industry-by-industry, state-by-state, community-by-community how best to reduce the harmful levels of pollution, it is certainly appropriate to consider cost, and I want to assure you that if these new standards are adopted, the EPA will work with all who are affected—State governments, local governments, community leaders, businesses, large and small, to find the common sense, cost-effective strategies.

For my part, I have written to all 50 of the Nation's Governors encouraging them to participate in the current standard-setting process, and should the revised standards be adopted, inviting them to work with the EPA on finding the solutions, on finding the ways to meet the public health standards.

I believe this Nation, and particularly its industries, can rise to the challenge. You, yourself, Mr. Chairman, cited our experience with chlorofluorocarbons. That is a great example of the industry doing far more than they ever thought they could do on the front end, of this country setting a bold public health goal and industry rising to the challenge. That is a story often told in the history of the Clean Air Act. We have done it, and we can do it again.

I am also aware that these proposed standards are controversial and that not everyone is happy with them. I would remind this committee, as I am sure you all know, that we are still in a period of public comment. We take seriously our obligation to carefully consider all of the comments before we make a final decision.

Finally, let me express my concern about the direction of the public debate. This is a vital issue of tremendous importance to millions of Americans, families and community after community. It is not about backyard barbecues or lawn mowers. It is not, as was heard on the radio this morning, about banning fireworks on the 4th of July.

Mr. Chairman, this is about whether our children will be able to go outside on the 4th of July and enjoy those fireworks. It is about finding ways in which we can all work together to ensure that the air we breathe is healthy, and that our standards protect the greatest possible number of Americans.

Over the history of the Clean Air Act, the goal is, and has always been, quite simply clean air—nothing in that has ever changed. What has changed is science, which is forever bringing advancements and innovations to improve the quality of our lives. Science now tells us that our air pollution standards are not adequate to protect our health.

Let us listen to the science, let us respond as we have before, let us work together toward common ground to improve the quality of air and to protect the health of our citizens. Let us do it for our children.

Thank you.

Senator CHAFEE. Thank you very much, Madam Administrator.

I would like to direct my first question to particulates, and it seems to me from the testimony we had the other day that this is an area where there are significant savings. I think in the prior—while you have here 20,000, I guess, I think the Lung Association says something like 60,000. I thought the EPA had come up with something like 40,000.

Administrator BROWNER. If I might explain, Mr. Chairman, the health estimates in terms of the number of premature deaths range from 40,000 to 60,000. The acid rain program, which the EPA, as you mentioned, is in the process of successfully implementing, will speak to some of the problems, the health problems, in this category so that the protections are in fact 40,000 premature deaths—20,000 because of this proposal, 20,000 because of the work that we're doing under acid rain.

Senator CHAFEE. Well, whatever it is, it is significant, certainly far greater than it seems we've been promised under what you're dealing with in the ozone, and you are familiar with that New York City chart that came actually from the scientists that were here the other day where they talk of in New York City, under the proposed regulations, the number of hospital admissions for asthma attacks would be 28,000 and would be reduced by something like 160 admissions.

But the point I'm making is it seems to me where we can really get a lot more for our investment is in the particulates, but we had—the scientists, both the chairman and the former chairman of the Advisory Board, both said that 5 years more science was required for them to determine exactly which particulates to deal with, and that during that time the monitoring stations would be built, and they would feel far more comfortable, and indeed they recommended—they said five more years.

Now what do you say about that?

Administrator BROWNER. Mr. Chairman, you raise, I think, a number of very important questions.

First, I would like to speak to the chart you referenced about hospital admissions. That is in fact a chart that is in EPA documents and has been made public over a long period of time. What is important to understand about hospital admissions is they are just the tip of the iceberg. They are one way, one measurement of the public health effect. You don't merely seek in proposing to strengthen standards to deal with hospital admissions. As this chart shows, for every hospital admission, there is in fact five-plus emergency or out-patient visits to the hospital. There are 20-plus

doctor visits, there are 100-plus asthma attacks. That is the protections that you seek to provide. It is not, I think, appropriate to merely look at the tip of the iceberg. That is one fact that has to be looked at. You should look at all the facts.

Senator CHAFEE. Yes, but you use a base. You use something as a base, and what you've used is a base in your own testimony, and the chart you submitted was hospital admissions, and you can work out a ratio there. In other words, here I am just quoting your own figures—"under the proposal, there would be 28,205 admissions a year in the New York City area and that would be reduced by 120."

Now, presumably, the same percentages would apply right down to non-hospital admissions and attacks, but my real point is here from your own testimony you're really making savings or prolonging life, whether it is 40,000, or 60,000—I guess you say the figure you're using is 40,000—and that is a big figure.

But, getting back to my—the two leading scientists who were here before us, the chairman and the former chairman of CASAC, said "we need more study on this."

Administrator BROWNER. Can I explain something about the science here because I think this is extremely important?

First of all, CASAC in their letter of closure to the Agency said, and we can give you a quote, that "an adequate basis for regulatory action does exist." They said that. All the scientific community, I think, would agree that further scientific understanding of the how is important, but that doesn't change the scientific recognition of cause and effect, and let me be more specific here. What the science shows is when 2.5 reaches certain levels in outdoor air hospital admissions go up, respiratory illnesses go up, deaths go up. You have a cause and you have an effect.

Now the science is still looking at the how, what happens, what exactly happens, but the effect is very clear. 2.5 reaches certain levels, people become ill, and unfortunately some number, a large number of people die. This is not dissimilar to the discussion over the last 20-plus years in this country when it came to smoking and lung cancer. We knew and the science showed us very early on that if people smoked, there was a high likelihood they would get lung cancer—that we knew. We couldn't tell—today we can't even tell you every single scientific step in the process, physiological and epidemiological step in the process. It doesn't change the fact that when you measure 2.5 in the air, people become sick, and I don't think it changes the need for action that you cannot explicitly spell out the how. You have a cause, you have an effect. That is what the law envisions, and that is what we seek to protect against, which is that effect—those premature deaths, those aggravated asthmas, those respiratory illnesses.

Senator CHAFEE. Thank you very much. My time is up.

Senator BAUCUS.

Senator BAUCUS. Thank you, Mr. Chairman.

Secretary Browner, the CASAC Committee said that the acceptable range for new standards in the ozone is between 70 and 90 parts per billion, and essentially it is a policy call as to what the new standards should be.

My question to you is what factors determine your policy call, not only with health effects, but obviously you have to look down the road and think about costs, think about practicality, even though technically States with their State implementation plans the more directly affect the cost side of this?

What were the considerations that led you to come to this policy decision, the policy recommendation, of what the ozone standard should be, and how did you reach it? What did you weigh and what was your final decision? How did you reach that decision? We know what your decision was but how did you reach it?

Administrator BROWNER. Quite simply, the science, the number of people affected, the number of people that would be protected and the requirement in the law that we set a standard with an adequate margin of safety.

What the science shows is far too many people are suffering adverse health effects under the current standards. I think it is important to understand that CASAC is made up, as I said earlier, and I think as you all know, of a variety of experts. Dr. Wolff is an industry representative. The medical health experts on CASAC, of which there were four on the ozone panel—there are atmospheric experts, there are other types of experts—but there were four health experts. Three of the four health experts said .08. The final health expert, the fourth one said .08 to .09.

So it was the science, it was the people affected, the health effects they experienced and the medical experts—those people who have committed their lives to studying the human health side of this saying .08.

Senator BAUCUS. Did you look at anything beside the health policy, anything else? Did you look only at the science, what those health scientists said, anything beside health?

Administrator BROWNER. We are driven by the science in this case. That is what the law requires and that is what we did.

We did do a cost-benefit analysis. The law is very clear. The interpretations of the law over the last 25 years are very clear. This is a public health decision. It is not a cost-benefit decision. So we make our proposal based on the science, the health effects, the medical experts and the law.

Senator BAUCUS. But, obviously, the more people that need more protection the higher the standard. So if you were looking only at health effects, you would have a tighter standard.

Administrator BROWNER. There are—obviously, those who have suggested that you could go to .07, you could go to .06. Where the science takes us is to .08, and that is why we propose it. When you look at—and CASAC did discuss a full range, as you said yourself, and the medical health experts, after that discussion, three out of four said .08, and that, for me, was very, very compelling science.

Senator BAUCUS. If you look at a curve, the number of people protected moved from, say, 9.9—.09 to .08 is significant, but when you move from .08 to .07, the number, the proportionate number of people protected falls off significantly.

Administrator BROWNER. I mean, there are changes in the number of people you are protecting. The scientific uncertainty as you get down to the extreme become greater.

Senator BAUCUS. Is that one reason why you came up with .08? That is my question.

Administrator BROWNER. The science takes us to .08, exactly, as you said.

Senator BAUCUS. OK, my second question deals with the Regulatory Flexibility Act. As you know, the law that Congress passed recently says that agencies must do a regulatory flexibility analysis of major regulations, and the EPA has concluded that this is not a major regulation for the purposes of the Act—namely, that, first of all, it's the States that implement this, which is a bit legalistic in my judgment, and, second, there is a problem historically because the EPA does not do an analysis of State implementation plans anyway once they come back.

As you know, several Senators have written you letters and are quite concerned about this—that is, the position of the EPA. It seems a bit legalistic, and, as I understand it, the EPA has revised its view on how it's going to approach this under the Regulatory Flexibility Act.

Could you tell us where you are with respect to that Act's provisions and this proposed regulation?

Administrator BROWNER. The Small Business Regulatory Flexibility Act, we believe that we are complying with the intent of that law. What that law requires is really two things—one is to work with the small business community, and we are doing that. We are working through the Small Business Administration to bring in small businesses, to meet with them, to look at how when you move to an implementation phase—again, we're on a public health phase, but when you move to an implementation phase to begin to build that dialog, to begin to build that relationship so that we can find the cost-effective solutions.

Senator BAUCUS. I guess it's important at some phase in this analysis that you look at the affect on small business.

Administrator BROWNER. We have, and, in fact, in the cost-benefit analysis we do speak to that, and we are, as I said, working with the SBA and small businesses to ensure that they are part of the very important dialog that would be necessary for any implementation.

Senator BAUCUS. We will be watching that, and I appreciate that.

Thank you.

Senator CHAFEE. Senator Inhofe.

Senator INHOFE. Thank you, Mr. Chairman.

Well, let me go back to what we were talking about before and touch on a couple of things that Senator Baucus was trying to penetrate there.

Drs. Wolff and Lippmann a week ago today—let me go ahead and read the quotes of Dr. Lippmann. He said,

Five years to answer many of these questions. I'm sure there will be some that will have further questions 5 years down the road, but 5 years is the minimum time to have a considered, well-designed, well-executed program of lab work in epidemiological studies. It takes a long time to do it, a long time to analyze it. It takes a long time to go through peer review work. I would say that 5 years is a good time-frame.

Then Dr. Wolff, who is the chairman of CASAC, said,

Based on our experience with peer review, I think we can frame the questions that need to be addressed in the near term, but, unfortunately, we don't have very many measurements of PM_{2.5} right now. We're going to need those measurements so that we can answer those questions.

Senator BAUCUS. Is your microphone on? I'm sorry.

Senator INHOFE. Again, he concludes, Dr. Wolff, "My own personal feeling is that we're talking about a 5-year timeframe to find answers to these questions." Now I also have found, Administrator Browner, in reading statements—I guess it was a deposition in the law that we have been quoted so often—you said,

The schedule developed by the EPA is based on the Agency's detailed consideration of each task necessary to review, and, if appropriate, revise the criteria and the national ambient air quality standards for particulate matter and a rigorous assessment of the minimum amount of time needed to accomplish these tasks. The EPA schedule provides for notice of proposed rulemaking by September 1, 1997, and final action to be December 1, 1998. Any shorter timetable would require the EPA to reach conclusions on critical scientific and policy issues with enormous consequences for society before it has had adequate opportunity to collect and evaluate the pertinent scientific data. In short, it would force the Agency to take procedural or analytical shortcuts that could jeopardize the EPA's ability to make scientifically sound and legally defensible decisions in the current review.

And just the other day when you were requesting \$26.4 million during the budget process, which I guess was in the President's budget, you said,

To reduce a great uncertainty about PM's health effects, the EPA will continue its efforts to identify the mechanisms by which particles affect human health. It will launch research into these areas.

Now are you weighing the relationship effects and PM exposure; two, determining the amount and size of particles inhaled and retained in your lungs; and, three, investigating biological mechanisms by which PM concentrations in outdoor air may induce health effects, and, in doing so, evaluating potential links between PM exposure and health effects?

Now, during the last committee meeting, we talked about that—the fact that you have to have either a reasonable, statistical connection or the biological mechanism, and in this case you have neither.

Let me finish here, first. It is my understanding—I asked them to give it to me but they didn't have it—but it is my understanding also that the Flexibility Act to which Senator Baucus refers requires you to—and it refers to small entities, which is individuals, as well as businesses—to advise them of the consequences of proposed changes in rulemaking. So, I have felt—and, Ms. Nichols, I have read your very complicated 3-page letter and have concluded that I didn't agree with your conclusions.

[Laughter.]

Administrator BROWNER. Senator, you raise a number of points, and I will try and respond to all of them.

The first document I think you are quoting from is a document that was filed in a legal proceeding more than 3 or 4 years ago—I'm not sure—and if you actually have the date, that might be helpful.

Senator INHOFE. Yes, it is proceeding before the court in 1994.

Administrator BROWNER. Right, and at that point, just to refresh everyone's memory, there was litigation filed by the American Lung Association because of their frustration that, unfortunately, the

EPA had not been able to complete the requirements of the Clean Air Act to do a 5-year review. They went to court and they said to a judge, "Force them to do this." It is something that I agreed that we should do, and then we, working with the judge, working with CASAC, laid out a schedule that everyone has agreed to, and we have been adhering to that schedule. Those pleadings were filed before an agreement was reached on a schedule, and they were filed 4 years ago, and I think that is important to keep in mind here. They are not pleadings filed in the last 1, or 2, or 3 weeks. They were filed several years ago.

Senator INHOFE. But you said final action by December 1, 1998. Any shorter timetable would require the EPA to reach conclusions on critical scientific and policy issues without the scientific data.

Administrator BROWNER. As is often the case in litigation, parties make their arguments. You reach a resolution and then you abide by the judge's order. That is what we are doing here. In no way does our desire to abide by a Federal judge's order suggest that we have not done the kind of detailed analysis envisioned by the Clean Air Act or that CASAC did not do their job.

CASAC gave us their letter of closure. They were very clear in terms of 19 of the 20 member said that we needed to set a 2.5, that we needed to focus our energies on 2.5, which I think is the second issue that you raised, this sense, again, that somehow or another there is a lack of science. This argument of the science has been around now for several months, and if I might just take a moment to explain the science, Mr. Chairman, that we have on 2.5. I think that could be very helpful to the committee. I know that the Senator's time is up, but I think this is an important question that we keep coming to the edge of, and if I might have a few minutes to actually explain the body of science that exists—

Senator INHOFE. That is up to the chairman, but if you come to the conclusion that adequate scientific data is there, that contradicts what was stated by both Dr. Lippmann and Dr. Wolff.

Administrator BROWNER. I have to beg to differ here, if I might.

Senator CHAFEE. We've got a big crowd here today, and we want to keep everybody to their time.

Administrator BROWNER. There are studies of literally hundreds of thousands of Americans. There are studies in more than 51 cities where the air was being measured, the amount of the fine particles, the 2.5 particles was in fact measured, and then the health effects recorded.

For people to suggest we have no 2.5 measurements, to suggest there are not health studies, is absolutely, positively not accurate. There are literally health records on hundreds of thousands of Americans, what happened to them when the air contained 2.5 at particular levels. It is a compelling body of science, and it shows there is a cause, 2.5, and there is an effect—hospital admissions, premature deaths—where all of us agree the science must now turn its attention is the how. The fact that you don't completely understand the how should not prevent us from providing the protection, from addressing the effects. It didn't prevent us in the case of lead poisoning. We couldn't tell you how children lost I.Q. points when we made the decision as a country to take lead out of our gasoline. We had a cause—it was lead in gasoline; we had an ef-

fect—it was children suffering, I.Q. points being lost—and we made the decision. It is only today, almost 20 years later, that we can tell you with any precision—and there are still studies going on as to how. The same is true here.

Senator INHOFE. A statistical association——

Administrator BROWNER. It's not a statistical association. It is not——

Senator CHAFEE. We've got to move on.

Senator Lautenberg.

Senator BAUCUS. He's not here.

Senator CHAFEE. Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

My colleague from California, Senator Boxer, has to leave and I have agreed to yield her 30 seconds.

**OPENING STATEMENT OF HON. BARBARA BOXER,
U.S. SENATOR FROM THE STATE OF CALIFORNIA**

Senator BOXER. Thank you, I will speak fast.

Administrator Browner, that is the best presentation that I have ever heard on the need to continue our quest for the cleanest possible air. I am particularly taken by the numbers of particularly the children who will be helped, and I do think that those who say, "just stay home on bad air days," they're surrendering. I will not surrender. My State has too much at stake, and I just wanted to make it clear that as we move on, I will work with you and the members of this committee to find out the science to move us forward, and I want to thank my colleague.

[The prepared statement of Senator Boxer follows.]

STATEMENT OF HON. BARBARA BOXER, U.S. SENATOR FROM THE
STATE OF CALIFORNIA

Thank you, Mr. Chairman, for calling this important hearing today.

Enormous progress has been made in the last twenty-five years to control and reduce air pollution and we must stay on the course of progress.

My state of California has a great deal at stake because our air in certain areas continues to be polluted. People feel the adverse impacts of that.

There are those who suggest that our children and adults with asthma should just stay home on bad air days.

Staying home and not going outdoors is not a remedy. It is surrender, and I don't believe in surrender. We must act.

The Clean Air Act directs the Administrator to set standards at levels that in the judgment of the Administrator protect the public health with an adequate margin of safety. That is her directive; that is her job. It is not to count votes in the Congress and then set the standard or to take a poll and then set the standard. She must set the standard at levels that protect the public with an adequate margin of safety. Health must continue or to be the marker upon which standards are based. And those standards must be based on science. Once health-based standards are set, then costs should play an important role in implementation and timetables.

Let me just say this about the cost issue. The debate over environmental regulations has continuously pitted the environment against industry, in an argument over whether the benefits of higher environmental standards are worth the costs they impose on our economy. I believe this is a phony debate because unfortunately in calculating these costs we never factor in the amount of money we save with higher environmental standards.

A recent article in The Washington Post on a study released by the World Resources Institute states, "When an investment is made or to reduce pollution two things happen: A cost is incurred, and other costs are averted. The fact that only the incurred cost is counted in measuring productivity means that environmental regulation lowers productivity not in reality, but by definition."

We must keep that in mind.

Mr. Chairman, I am going or to work aggressively or to pursue answers or to the serious questions that have been raised about the EPA proposal and I look forward or to working with you, Administrator Browner, as well as this committee.
Thank you.

Administrator BROWNER. Thank you.

**OPENING STATEMENT OF HON. JOSEPH I. LIEBERMAN,
U.S. SENATOR FROM THE STATE OF CONNECTICUT**

Senator LIEBERMAN. Thank you.

Thank you, Administrator Browner.

Since we didn't have time for an opening statement, I'm going to mostly talk and maybe ask you one question toward the end because I think this is critically important. I think it is very important to restate what you have stated, which is that in promulgating these standards, you are doing your job as we in Congress have defined it. This is not some personal lark you are off on.

Administrator BROWNER. That's true.

Senator LIEBERMAN. You have been ordered by the statute, which was adopted by Congress to come back every 5 years and ask what science technology, public health experience tells us about the impact of dirty air on the health of the American people, and you have done that because the standard adopted in this law, as you corrected pointed out, on a bipartisan basis, starting under President Nixon, taking a significant step forward under President Bush—and I was in that room, in the Senate Majority Leader Mitchell's Office with Bill Reilly, with Boyd and Gray, with a whole group of people from the Administration, Senator Chafee and others, both parties; Senator Baucus, obviously, negotiating this—this is all about health. And, as you correctly stated, the second phase of this when you begin to implement it, is what is the practicality? What is the cost? How do we do that?

As I said last week at the subcommittee hearing, Fairfield County, CT, southwestern Connecticut, has some of the dirtiest air in America. A lot of it has to do with air blowing up from other States. A standard that is health-based has been set for Fairfield County, but in the interest of reasonable unfair implementation, that county has 17 years to reach that standard. So the question before us, I think—and what Senator Baucus has correctly described as an early stage of the process here, and let's not reach premature judgment—is, is your fulfillment of the job we've given you being done in a reasonable manner? In other words, do the health statistics and experience show us that unless we adjust the standard, as you say, a lot of people are going to get sick and some are going to die earlier than they would otherwise die unless we make this change. We can come back and decide what is appropriate and what's fair in terms of implementation, but if we determine that you've got a scientific basis, as most of CASAC did, for these standards that you put before us based on all those studies, then we've got to ask ourselves, what is our obligation?

Are we going to tell the American people the truth or are we not going to tell them the truth? Now, that is the process that we're involved in, and I don't think any of us have been far enough into it to reach a conclusion.

I do want to say about Senator Chafee's statement this morning, his statement in the press this morning, and I say this respectfully because I have enormous respect for Senator Chafee, I was very disappointed to read those statements. "With the tighter standards, you're going to find to revolt against the Clean Air Act," Senator Chafee told reporters.

I don't see it. There may be a revolt among the regulated industries that fear the cost of this. I understand that, and that is something we have to consider as we go forward, but a revolt among the American people based on the fact that we're trying to find a rational basis for protecting their health—I don't see it. Overloading the horse, getting the whole program in jeopardy, this is a program that has broad support among the American people.

We were talking—I think it was Ms. Nichols and I. I did a show with a radio talk show host—this was about 3 or 4 years ago—and he wanted to talk about the Clean Air Act, and he said, "You know, I am a conservative. I'm a conservative Republican, but let me tell you this. If there is one thing my government should do for me and my family, it is to make sure that we breathe clean air and drink clean water," and I think that is what this is all about.

Now, the yellow light is on. My question is let's go to the most unsettling of the conclusions you've reached. What is the basis for concluding that the particulate matter standards you're proposing will prevent 20,000 premature deaths annually?

Administrator BROWNER. If I might put a chart up showing you the human health effects peer reviewed, published scientific studies that have been done. As I said before, literally hundreds of thousands of people have been studied, what happens when 2.5 reaches certain levels of concentration in the air. What it shows, what each and every study shows are large numbers of people affected. I mean, these studies—the base of knowledge we have on 2.5 is extremely large. You can see how many people were studied in each of these instances—

Senator LIEBERMAN. Ms. Browner, if you could give some numbers because I don't think members of the committee can read that.

Administrator BROWNER. In the one study involved approximately 2.3 million people; another study, 2.4; another study, more than a half million. I mean, the numbers go on and on. They cover a large number of cities, an excess of 51 cities are measuring 2.5, and what it shows you are extreme effects—deaths, premature deaths, respiratory illness, aggravated asthma. The standard that we proposed in keeping with the requirements of the law are designed to guard against and to prevent those premature deaths. Because it is death, because it is so severe, we do it with a margin of safety, as the law directs us to.

If I might, Senator, just take a moment to go back to a point you made in your comments. I think inherent in all of our environmental statutes is the public's right to know, which is something I have worked very hard to honor over the last 4 years. Most particularly I think the Clean Air Act spoke to the public's right to know when it ordered a 5-year review. It didn't want—I think the Congress didn't want, three Presidents who all signed this provision, didn't want a situation of the American public not knowing the quality of their air. So not only do we do this because it is

where the science takes us, we do it because we believe the public has an absolute right to know. Moreover, as I think you pointed out, there is no rush to judgment here. This is 10 years of science. We have been about this process in one way or another for more than 10 years now.

Senator LIEBERMAN. Thank you.

Senator CHAFEE. I knew there was trouble ahead when Senator Lieberman started off by saying he had the greatest respect for me. I was braced for that shoe to drop.

[Laughter.]

Senator CHAFEE. I would point out that probably the most cost-effective and effective step that we could take in the United States of America to deal with dirty air is to have inspection and maintenance of our vehicles, and we had that in the law. When we talk about revolt, there is the perfect example. State after State, including California, repealed statutes they passed dealing with inspection and maintenance. So did my State of Rhode Island. I think Connecticut—somebody told me that Connecticut and Oregon were the only two that didn't repeal it, and they went through with their inspection and maintenance.

But there is the perfect example of what my concern is, and it isn't something to be taken lightly. Everything in the Clean Air Act is written in concrete, it's going to stay there forever—not at all. If you press this thing too far too fast, there are going to be steps taken by the American public, as we saw in that inspection and maintenance, which was very sad to see take place.

Administrator BROWNER. Mr. Chairman—

Senator CHAFEE. We've got a tremendous—we've got a big group here, and if you want—

Senator LIEBERMAN. Let her make this one comment.

Administrator BROWNER. One minute, thank you, Mr. Chairman.

Just briefly, when I came to the EPA, I recognized that you couldn't apply a one-size-fits-all solution to local air pollution problems, that you had to work in partnerships with States and local government to find what made the most sense for them, and we developed a long menu of options that Governors, mayors, communities can choose to reduce their air pollution.

It is true—if you do a simple cost-benefit analysis, getting your car inspected will turn out to be the cheapest way to clean up the air. That is true. That is what a cost-benefit analysis will tell you—\$500 a ton as opposed to something on the order of \$2,000 to \$10,000 a ton for any other solution out there today.

But we recognize for some communities, quite frankly, they wanted to make a different choice, and we provided the flexibility to design the programs. I think it is important to understand when given the flexibility, many communities did choose to have automobiles inspected. They did choose to say to their citizens, "help us, spend 20 minutes every other year, maintain your car, get it inspected," and in fact—I don't like to disagree with you, Mr. Chairman. I have the utmost respect—

Senator CHAFEE. Oh, here we go again. I think I'm going to cut you off.

[Laughter.]

Administrator BROWNER. But California does have a tailpipe inspection program, with all due respect, and I think Connecticut also has such a program in place.

Senator CHAFEE. I said Connecticut did—Connecticut and Oregon.

Administrator BROWNER. I apologize.

Senator CHAFEE. Senator Kempthorne.

Senator KEMPTHORNE. Mr. Chairman, thank you very much.

Senator REID. Senator Kempthorne, would you yield just for 15 seconds?

Senator KEMPTHORNE. Senator Reid, do you have the utmost respect for me?

[Laughter.]

Senator REID. I'm sorry. Thank you very much, Senator Kempthorne.

Mr. Chairman, I have been called to a Capitol meeting, and I ask unanimous consent that my full statement, together with a series of questions, be allowed to be inserted in the record and that the Administrator would answer those at her convenience.

Administrator BROWNER. Certainly.

Senator CHAFEE. Fine, and there will perhaps be other questions submitted.

Thank you for coming, Senator Reid.

[The prepared statement of Senator Reid follows:]

STATEMENT OF HON. HARRY REID, U.S. SENATOR FROM THE
STATE OF NEVADA

Thank you, Mr. Chairman. I appreciate you scheduling today's hearing on EPA's proposed regulations on ozone and fine particles. This issue has received a great deal of public attention and I believe it is very important that we examine very closely the arguments both for and against this proposal.

The Clean Air Act is a cornerstone of this nation's environmental protection program and one of the crowning achievements of this committee. Like most members, I am pleased that while our nation's population has grown, our air, in most instances, has started to get cleaner. Nationwide, air pollution from carbon monoxide, lead, particulates, and sulfur dioxide are down significantly.

In my home state of Nevada, home to the fastest growing city in the United States, Las Vegas, the maximum levels of carbon monoxide have fallen 35 percent in the last 10 years. So-called unhealthy days have fallen from more than 50 per year to less than 10.

Does this mean the air in Las Vegas is perfect. No. Far from it.

What it means is that we are making progress.

That progress is a direct result of previous Congresses and the EPA showing leadership when faced with a lack of absolute scientific certainty.

We are faced with a similar lack of certainty today. However, it is important that EPA and the scientific community clearly demonstrate that these new standards are justified. The processes we have in place to set national air pollution control policy has served this nation very well. It can be a long and difficult process, but it is one that has allowed us to make real progress during the last 27 years. Today's hearing is an attempt to make sure that the next steps proposed by EPA are ones that will net us continued progress.

With that said, Ms. Browner, I join with my colleagues in welcoming you here today. Before getting to the big question of the day, I have one small item to discuss. My state's Governor, Bob Miller, is currently chairman of the National Governor's Association. In that capacity, he wrote to you recently requesting that you extend the comment period on these regulations to allow all of the states and municipalities adequate time to review and comment on the regulations.

I thank you for asking the court for just such an extension last week. I understand they have granted a three-week extension of both the comment period and the final promulgation date for the particulate matter rule. I am sure the extra time

will help the folks we are expecting to help us implement these rules understand them a little better. Again, thank you.

Ms. Browner, although all of us sitting up here are going to ask it a slightly different way, it seems to me that the bottom line reads: "Is what you are doing necessary to protect public health with an adequate amount of safety?"

We have heard a great deal in recent weeks about the role of the Clean Air Scientific Advisory Committee and what they did and did not say. We have also heard many conflicting views about where science stops and where policy decisions start.

It is my hope that you will be able to shed some light on these issues.

Additionally, I am a Westerner. I also represent the fastest growing state in what is perhaps the fastest growing region in the nation. We are often concerned that the federal government, in setting national policies, adopts a one-size-fits-all approach that does not suit the needs of the states, localities, and people living in the West. In your remarks, or as a follow-up, I would like for you to address how, if at all, you have incorporated the unique concerns of Western states into your proposal.

I think I speak for the whole committee when I say that, when all is said and done, we are hoping to see strong factual and scientific conclusions leading to reasonable policy judgments by you and the rest of the professionals at EPA we have charged with making just these sorts of hard decisions. Thank you, Mr. Chairman.

Senator CHAFEE. All right, Senator Kempthorne.

**OPENING STATEMENT OF HON. DIRK KEMPTHORNE,
U.S. SENATOR FROM THE STATE OF IDAHO**

Senator KEMPTHORNE. Mr. Chairman, thank you very much.

Madam Administrator, I would hope that the EPA will re-evaluate the economic impacts of the proposed standards under both the Unfunded Mandates Act and the Small Business Regulatory Enforcement Fairness Act.

While the Clean Air Act requires standards to be set without regard to cost, it does not prohibit the EPA from identifying and assessing the real life impacts of the proposed regulation. Both the Unfunded Mandates Act and the Small Business Regulatory Enforcement Fairness Act are based on the principle that the public has a right to know, which I am delighted to see you're a staunch advocate of. A regulating agency should know as well the costs of regulation, even when those costs are not specifically factored into the regulation itself.

The EPA should undertake an analysis of those costs under the unfunded mandates law, after all because that is good responsible government.

My question is will you do so?

Administrator BROWNER. We agree with you, and in fact we have done a cost-benefit analysis on these proposals. As you point out, the statute requires us to make a public health decision, not a cost-benefit decision. But because I believe, as do you, that it is an important part of the debate, an important part of the discussion, we did in fact conduct and made available to the public a cost-benefit analysis. I think something on the order of 2,400 copies of this analysis, which is quite long, have been requested and delivered to members of the public. It is on the Internet and anyone can access it.

I think the question perhaps that you raise is the question of unfunded mandates and what the law actually requires in terms of cost effectiveness termination unless the law prohibits, and, as I think the courts have rightfully interpreted, the section of the Clean Air Act that speaks to public health, it is a public health decision and not a cost-benefit decision. We did do the study, and it

is publicly available. I think it is extremely important to understand that when you conclude the public health phase and begin the implementation phase, cost benefit is front and center. You use cost benefit to make judgments in terms of should it be this industry that reduces their pollution or another industry. What is the cost?

The final thing, if I might, Senator, just point out is that this issue of cost and benefits under the Clean Air Act has been an issue for many, many, many, many years, and every single time the Congress, every single time the EPA joining with the Congress has sought to tighten the public health standards under the Clean Air Act, we have heard from some in the industry that the cost would be prohibited. The facts are actually different. In each and every instance the cost of reducing pollution under the Clean Air Act has proven to be far less than anyone suggested on the front end, and the benefits far greater.

We have a study right now under peer review that shows the benefits under the Clean Air Act for a 20-year period 45 times greater than the cost. There is a good history here of industry rising to the occasion.

Senator KEMPTHORNE. OK, and I appreciate very much that you're doing the cost-benefit analysis. As you know, that was a critical part of the Safe Drinking Water Act, and we worked on that together.

My question, in addition to the cost benefit though is, have you determined the costs to the States and the local communities that must implement these new standards?

Administrator BROWNER. You're asking me a question in terms of what it cost then to write a plan? Is that the question you're asking? I apologize—

Senator KEMPTHORNE. Whatever the requirements are that you would place on to the governments, what is the cost for them to implement?

Administrator BROWNER. We are looking at the cost. I think what you're asking is there is—obviously, what States do is they develop a plan to reduce pollution, to meet a public health standard. The actual number of staff people involved, the work they do, is a cost we are now looking at with the States, and it will be in the next updated cost benefit analysis. As we get more information in during the public comment period, we do, obviously, revisit these documents and make improvements, and we are doing that.

Senator KEMPTHORNE. And too I would like to visit those documents too.

Administrator BROWNER. OK.

Senator KEMPTHORNE. So would you make available then what is the cost to States and local governments to implement monitoring devices, etcetera, so that we know what is the cost, and also what is the cost to business? It follows the concept of the Unfunded Mandates Act, which has been now made the law of the land.

Administrator BROWNER. Right, we agree. What we could do this afternoon is deliver to your office the cost-benefit analysis as it now stands. Again, this is available on the Internet to the American people. Many people have accessed it, and then as we conclude the public comment period and make improvements based on new

knowledge we have received, we will also make that available to the committee.

Senator KEMPTHORNE. OK, my time is up, but just so that we have an understanding, the cost benefit is one report; the actual cost, another report.

Administrator BROWNER. The way I think we are approaching this, and we can talk to your staff about it just to make sure we have an understanding, is that we are I think developing one document that speaks to all of the issues, but we'll work with your staff.

Senator KEMPTHORNE. All right, thank you very much.

[The prepared statement of Senator Kempthorne follows:]

STATEMENT OF HON. DIRK KEMPTHORNE, U.S. SENATOR FROM THE STATE OF IDAHO

I want to thank you, Mr. Chairman, and the chairman of the Clean Air Subcommittee, for holding this hearing on EPA's proposed new air quality standards for ozone and particulate matter, for surely there is no more important issue to all of us than breathing clean and healthy air.

It seems self-evident, but I believe that it is a point worth emphasizing—All of us here today, Republican and Democrat alike, are committed to protecting our environment, our air, our water and our natural resources. This is not, and should not be a partisan issue.

No one wants to see children suffer from asthma or miss school because of pollution in the air. No one wants to see tens of thousands of Americans die prematurely because of air pollution. So, should we have the most stringent air quality standards necessary to protect public health? Of course.

But, in Administrator Browner's own words, our air quality standards must be based on "the very best science to do what is necessary to protect public health in common-sense, cost-effective ways." That is a goal that we certainly all share.

After reviewing EPA's proposed standards, however, I am concerned that we don't yet have "the very best science" to ensure that the standards will address the real health risks, if any, that may be posed by ozone and very fine particulate matter. It is troubling that only two of the ten members of the independent scientific review committee, CASAC supported EPA's proposed standard for ozone. It is equally troubling when the CASAC panel also could not reach a consensus on what standard would be appropriate for PM_{2.5} because there were "many unanswered questions and uncertainties regarding the issue of causality."

And yet, EPA appears prepared to proceed to finalize new standards on an expedited schedule, not because it has the "very best science," or clear evidence of significant health benefits to be gained, but because of a lawsuit and a court-ordered deadline.

At the very least, it seems that EPA's action is premature. While I recognize that under the current law, EPA is required to set air quality standards at a level that will ensure public health protection with an adequate margin of safety, without regard to cost, the record here suggests that EPA does not have the scientific information that is necessary to ensure that its standards will, in fact, ensure public health protection. For example, CASAC's review of EPA's proposed standard for PM_{2.5} demonstrates that we need better science on very fine particulate matter and specifically which small particulates cause health problems. Without better scientific knowledge, we could find ourselves in the position of forcing communities and businesses to spend hundreds of millions and even billions of dollars without ever addressing the real health threats. Similarly, CASAC's failure to support EPA's proposed ozone standard suggests that the scientific basis for lowering the ozone standard is at best questionable.

These new standards, if finalized, will impose substantial new costs and burdens on states and local governments, communities, small and large businesses, and even individual citizens. Before the Agency rushes to finalize any new standards, I believe that it must address concerns that have been raised regarding whether there is sufficient science to proceed with these rulemakings at this point, or whether further studies are needed to ensure that the goals of the Clean Air Act are met.

I would hope that EPA will also reevaluate the economic impacts of its proposed standards under both the Unfunded Mandates Act and the Small Business Regulatory Enforcement Fairness Act. While the Clean Air Act requires standards to be set without regard to cost, it does not prohibit EPA from identifying and assessing the real-life impacts of a proposed regulation. Both the Unfunded Mandates Act and

the Small Business Regulatory Enforcement Fairness Act are based on the principle that the public has a right to know, and a regulating agency should know, the costs of regulation, even when those costs are not specifically factored into the regulation itself. EPA should undertake an analysis of those costs under the Unfunded Mandates law; after all, that's just good, responsible government.

I look forward to hearing Administrator Browner's testimony this morning and I hope that she will address these issues.

Senator CHAFEE. Senator Allard.

Just so that everybody will know where they stand on the early bird, next we'll be followed by Senator Wyden, Senator Sessions, Senator Smith, Senator Boxer, and Senator Thomas.

[The prepared statement of Senator Thomas follows:]

STATEMENT OF HON. CRAIG THOMAS, U.S. SENATOR FROM THE STATE OF WYOMING

Thank you, Mr. Chairman, for holding this hearing to continue our discussion of the EPA's proposed rule for Particulate Matter (PM) and Ozone. I certainly agree with you that what we are considering today is quite possibly the largest, most important regulatory action undertaken since the creation of the Clean Air Act. It is a pleasure to have EPA Administrator Carol Browner with us and I look forward to her comments and testimony.

If there was one consensus reached in last week's hearing on the science behind these proposed regulations, it's that there is no consensus. Dr. George Wolff, the current chairman of the EPA's Clean Air Scientific Advisory Committee (CASAC), stated that the court-ordered deadline did not allow enough time for members of the panel to adequately examine this complex issue. Dr. Morton Lippmann, Professor of Environmental Medicine at New York University Medical Center and, former CASAC chairman, also stated that more time is needed to conduct additional research. At one point, both scientists were bickering back and forth about what "was" and what "was not" agreed to by the panel of scientists.

In the Clinton Administration's budget request for Fiscal Year 1998, the EPA is seeking \$26.4 million for—and I am quoting here—"research to reduce the great uncertainty about PM's health effects." If we are not absolutely sure about which particles we should be regulating, should we really be seeking to impose new standards? Is there a rush to judgment? The request goes on to state that EPA "will launch research into three areas: (1) evaluating the relationship between the health effects and PM exposures; (2) determining the amount and size of particles inhaled and retained in the lungs; and (3) investigating biological mechanisms by which PM concentrations in outdoor air may induce health effects and, in doing so, evaluating potential links between PM exposures and health effects." I think this clearly demonstrates the EPA's need for more time and scientific research to study this controversial issue.

This is not about new standards for backyard cookouts or gas powered lawnmowers. Instead, it's about possibly implementing a standard based on inexact science and inconclusive evidence. If we can effectively end health risks for people and children we should do it. But we shouldn't step off this cliff merely because we hope and theorize that these new standards will offer us the results we want.

CASAC stated that "our understanding of the health effects for ozone is far from complete." The members also documented that "there was no scientific consensus on the level, averaging time, or form of a PM_{2.5} National Ambient Air Quality Standard (NAAQS)." With all of this ambiguity, and a lack of scientific data—which was documented by the experts who testified last week—it seems that EPA's decision to set new standards for PM and ozone was a judgment call, not a result of sound scientific evidence.

Mr. Chairman, it is paramount that principles of sound science are being applied. As we all know, this is a very technical issue and we need to be confident that the choices we are making will get to the heart of protecting public health. I am concerned, however, that we are about to go down a regulatory road before we truly know which pollutants are causing health effects.

No one is rejecting the notion that we need to continue to look for ways to improve and protect public health. However, that concept needs to be balanced with the best available, peer-reviewed science. It ends up building support for whatever measures we take because folks will have the confidence that the sacrifices they are making are really worth something.

Mr. Chairman, we all want to protect public health and the environment. Folks in Wyoming enjoy clean air and take pride in living in a state where current

NAAQS are being met. However, if these proposed regulations are implemented, Wyoming could get caught up in a major sweep and be required to implement standards that may actually yield few health benefits. Again, I compliment the chairman for holding this hearing and look forward to hearing from our two witnesses.

Senator CHAFEE. Senator Allard.

**OPENING STATEMENT OF HON. WAYNE ALLARD, U.S. SENATOR
FROM THE STATE OF COLORADO**

Senator ALLARD. Thank you, Mr. Chairman.

I would like to request that my remarks be made a part of the record.

Senator CHAFEE. Absolutely.

[The prepared statement of Senator Allard follows:]

STATEMENT OF HON. WAYNE ALLARD, U.S. SENATOR FROM THE STATE OF COLORADO

Thank you Mr. Chairman. I'm pleased to have Administrator Browner with us today to go over this important and complicated issue. Last week in my opening statement I expressed the hope that we could settle the science in this area so we could discuss the policy with Ms. Browner.

Unfortunately, that didn't happen, and in fact, there may be more questions about the science now than before that hearing. So today instead of discussing policy I hope Ms. Browner is prepared to help us with the science that led her to believe these regulations were necessary.

In particular she should be able to tell us why the CASAC panel was so divided on the PM issue. To some it would appear that instead of taking sound science EPA is merely taking sides. For example, last week the Clean Air Subcommittee was treated to an exchange between two prominent scientists who serve on the CASAC panel. This exchange basically devolved into a "yes-this-is-true-no-that-is-not-true" debate. Unfortunately, this type of exchange could lead to a perception that science has less to do with these regulations than ideological viewpoints. While I don't believe that is true, I do believe we need to move very cautiously to ensure that cynicism doesn't become widespread; because if that becomes the case more people will take the view of one individual who commented that, "It's apparent from this regulation that the EPA doesn't want us driving our cars across the bridge to the 21st century."

Thank you Mr. Chairman.

Senator ALLARD. I also have some questions that I would like to submit for Ms. Browner to respond to, if she would please.

Administrator BROWNER. Certainly.

Senator ALLARD. In the meantime, I will cover, hopefully, some rather fundamental issues here for the committee.

You used the words,

"There would be 133 million people helped with these rules"—

Administrator BROWNER. Protected.

Senator ALLARD. Protected with these rules and regulations. The testimony that we had earlier from your advisory council with Senator Inhofe stated that this scientific data was directed toward those people who are suffering from some type of disease disorder. They had asthma—you mentioned this here—they had asthma or you talked about special risk populations, such as children, and then you made in your statement, "There is a 133 million people that would be helped."

There's 260 million people in the United States, so I'm curious as to how you came up with 133 million.

Administrator BROWNER. Well—

Senator ALLARD. If you look at your neighbor, they have asthma, their child or—I mean, where do you come up with 133 million? I

looked in your testimony and I didn't see that written in your testimony.

Administrator BROWNER. First of all, healthy people, non-asthmatics, can experience and do experience, the science shows that they experience, under certain levels of pollution adverse health effects—

Senator ALLARD. That is correct, certain levels of pollution, but what you talk about for ozone and for particulate matter—in the previous panel I asked them the question, well, how about normal people? Will these affect normal people? They didn't think that they did. They said that these are figures that are directed at people that show signs of disease or have some disease—

Administrator BROWNER. With all respect, many of the studies focused on quote normal people in the real world. It looked at what happened to the child.

Senator ALLARD. OK, well, then let me—then you mention 133 million. How come—if only half of the population is affected, how come the other half isn't?

Administrator BROWNER. Because, fortunately, for half of the American people they are living in a place where the air already meets a cleaner standard. They are fortunate to live in a place where the levels of pollution do not exceed what the science shows us in terms of cost and health effects.

Senator ALLARD. Well, I just have to tell you as one member of this committee in listening to your figures, you seem to start out with somewhat of a good scientific basis, and then all of a sudden you begin extending your argument and all of a sudden you sort of exaggerate your figures—that's the impression I get—in your presentation.

So I'm trying to size down—

Administrator BROWNER. Well, let—

Senator ALLARD. Just a minute, if you would please.

Administrator BROWNER. OK, I apologize.

Senator ALLARD. I'm trying to size down what the real problem is and where we can really make a difference.

Now, I'm thinking as a legislature, a senator from the western part of the United States, and you have asked local governments to implement the Clean Air Act, the clean air standards. Will local governments have an opportunity to tell Federal agencies what they need to do to comply with this?

Administrator BROWNER. There is a process which will, as you move into the implementation phase, through—we have a panel we use—and I want to get the name right—a Local Government Advisory Committee. I personally meet with them regularly. We talk about drinking water frequently, and hopefully we will talk about it less now that we have a new law. But that will be one mechanism for soliciting the input of local government, one of many.

Senator ALLARD. The input of local government, but I'm talking about the implementation of the Clean Air Act.

Administrator BROWNER. That's what I'm saying, right.

Senator ALLARD. So if the Forest Service, or BLM, decides to have a natural burn on forest that increases particulate matter, concentration in the air, and it has an impact on the total effect because this hangs around States like Colorado not for a week, or

2 weeks. It will hang around for 1 to 1½ months during the fire season, and this is going to have an impact on what happens in those communities.

So local communities somehow or another are going to tell the Federal Government, the forest or the BLM that you can't cause the fire to burn because it does have an impact on our standards, on particulate matter?

Administrator BROWNER. There are many processes already in place and others that will be added to ensure that all of the parties with an interest on the implementation side are part of the discussions. For example, you raised other Federal agencies—an appropriate question. There is a process, the interagency process. In fact, Ms. Sally Katzen is here from the White Office with authority for managing that process. We are in dialog with other Federal agencies.

Senator ALLARD. You know, you talk around it but you don't really answer my question.

Administrator BROWNER. What is the question?

Senator ALLARD. The fact is, the point I want to make before this committee, is you have one agency out here—two agencies—that are doing things that impact ambient air quality and somehow or another they get excluded—they don't get considered in the process because what they are doing has an impact on local governments, and in particular in my part of the country, the Grand Canyon Visibility Project, it has an impact, and you need to recognize that.

My time has expired. I have a red light on there, and I would like to have more time to visit with you on these issues.

Administrator BROWNER. Senator, we do recognize the impact that the Federal Government may have on local communities. In fact, the Federal Government complies with drinking water standards where they operate facilities. We comply with waste water standards, we comply with MPDES. No one is suggesting that the Federal Government sits outside or the actions of the Federal Government in community after community sit outside the pollution standards.

Senator ALLARD. Mr. Chairman, I keep getting the last—are you an attorney? You keep working for the last word.

Administrator BROWNER. Well, with all due respect, I think I have a right to respond.

Senator ALLARD. Well, listen—

Administrator BROWNER. I don't have the right to respond? I'm sorry.

Senator ALLARD. You do have a right to respond, but I just want to make sure that you give local governments and States the right to talk about what some of these Federal policies are having on air quality. In your response to me you talked about clean water—we're talking about clean air, and we're talking about the impact of national burn on ambient air qualities in the States in the western parts of this country, and how it's going to affect those local communities.

I think that the Federal Government needs to be a partner in that. We need to do something about it, but they need to be a partner in it.

Administrator BROWNER. We agree. With all due respect, we agree, and, in fact, as I tried to explain, we have processes in place to ensure that that happens both at the local government level and with the Federal agencies. If there is advice that this committee would like to offer, or you would like to offer, in terms of other processes, we would be more than happy to consider those.

Senator CHAFEE. On a high note, with all due respect, we agree.

Administrator BROWNER. We agree, that's what we're saying—we agree.

Senator ALLARD. But you haven't—

Senator CHAFEE. All right. My father once told me never argue with analogies.

[Laughter.]

Senator CHAFEE. We'll now move on to Senator Wyden.

**OPENING STATEMENT OF HON. RON WYDEN, U.S. SENATOR
FROM THE STATE OF OREGON**

Senator WYDEN. Thank you, Mr. Chairman, and Ms. Browner.

To me this debate shouldn't come down to just the question of your health or your money. Our country made the wise judgment years ago. The Clean Air Act was going to be based on health standards. I don't think the country wants it changed. I would fight changing it. I think there are legislators on both sides of the aisle who don't want to see that compromised.

At the same time, I can list three or four specific concrete ways that once we keep the health foundation, we can look at ways to hold down costs. For example, in my area we like to give credit to parts of the country that have done the heavy lifting and are making progress. For example, and I want to be very specific on this, because I think it is important to find a way to come together after we have made the judgment that we want a health standard to look at ways to hold down these costs.

For example, we've got communities in Oregon that are very concerned that they've got to spend their time on paperwork getting officially reclassified as in compliance with 1990 standards rather than just bringing you the data showing that they are making the progress and moving on.

Can we start that discussion with some of those things and begin to bring people together around that point?

Administrator BROWNER. I agree, and, in fact, the question of redesignation is one that Ms. Nichols and her office has focused a great deal of energy on. We are now expediting those applications for redesignation. I think we have been able to reduce the time significantly from—unfortunately, it was taking years but we now have it down to months.

Senator I know you appreciate the fact that there is a process. It is not simply the EPA and the States saying yea or nay. There is a public comment and a public right to know mechanism embodied in a redesignation decision, and that does take a chunk of time in there, but I think the fact that we have been able to reduce it literally from years to months is an indication of our willingness to work with communities.

Senator WYDEN. What are your thoughts about expanding, for example, the trading of credit as another way, again, to bring people together as we look at an Act that has a health standard?

Administrator BROWNER. We would agree that emissions credit trading programs have been very, very successful. As I've said in answering some other questions, the history of the Clean Air Act is that the estimates of costs on the front end turn out to be much greater than the reality of the costs on the back end, and I just want to show you a chart.

We looked at three fairly significant decisions under the Clean Air Act. We looked at what people said it would cost us to solve the acid rain problem in the country and what it has actually cost us. The estimates on the front end range from \$1,000 to \$1,500 per ton. Today, you can buy a credit for \$78 on the Chicago Board of Trade. We looked at what it cost to produce a cleaner car. When we went to Detroit and said, "Make us a cleaner car," they said, "It's going to cost something on the order of \$1,500." That car is on the road today and it is costing between \$60 and \$100 a car.

Over and over again industry rises to the occasion. The cost of actually providing cleaner air comes down significantly from the estimates, and, equally important, the benefits of clean air are far greater than we could have ever estimated or guessed on the front end.

Now, I would also tell you there is a process. We are using a Federal Advisory Committee process to look at other streamlinings, other innovations, that we can make in the implementation of the law. What can we do to respond more quickly, to turn around the kinds of answers that the Federal Government and State governments need from us. We have a process underway.

Senator WYDEN. I've got my warning light on, and let me see if I can wrap it up this way.

I would like to submit to you, Ms. Browner, because you have been responsive to our State in the past and we've worked closely together about four or five specific suggestions in this area. I think it is important for us to talk about how to deal with regional differences. I think that it is important that we talk about how this is integrated in the whole debate about energy policy and energy deregulation.

My only concern is for those of us who feel strongly about keeping those health-based clean air standards. It is critical, in my view, to not make the discussions about implementation some kind of afterthought and just something that is going to be discussed another day. We're going to keep the guts of this Act. We're going to fight those who try to compromise it, but, at the same time, I think every step along the way we want to be looking at these kinds of ideas, and we will furnish them for the record in writing, and look forward to pursuing them with you.

Thank you, Mr. Chairman.

Senator CHAFEE. Thank you, Senator.
Senator Sessions.

**OPENING STATEMENT OF HON. JEFF SESSIONS, U.S. SENATOR
FROM THE STATE OF ALABAMA**

Senator SESSIONS. Thank you very much.

Administrator Browner, I think you are a great advocate for the position that you're taking. We have a little different perspective in the sense that we have to represent the people of our States, and we have to be sure that what we are asking them to sacrifice to do is actually going to get the kind of benefit and advantage that you predict that it will.

In that regard, I have some concern about the numbers. Senator Allard asked about the number of children protected, the number of people protected, and I think he said 133 million. But if you have that chart there of the smog and ozone, I think we had an agreement from all the scientists that were here last time that the present level of ozone and present levels for particulate matter are not really adversely affecting the health of healthy people. The focus has been on those who are sensitive in some way.

Isn't that a fact?

Administrator BROWNER. We can show you, I think, what CASAC said, if I might, just paraphrase what the scientists said, which is it is true. The current levels provide some level of protection, but they leave too many people at risk. There are too many premature deaths, there are too many aggravated asthmas, there are too many respiratory illnesses. That is what the science, the human health effect science shows us. It is not to say that all the work we've done hasn't been great and hasn't been necessary, but the science now shows us that we again need to take another step. We need to add another layer of bricks.

Senator SESSIONS. But we can go further. I will respect that, and I think we can go further, and we need to do that as we are able and as the science supports it.

But I was just looking at this figure. It has dawned on me that all the total protected Americans means is that that is the number—122 million people—who live in the areas of this country that will now be under some control if this law goes into effect, these regulations go into effect. That is what you mean, and I would just suggest to you that that overstates in the minds of most of us when I first saw it the real benefits that we might be getting from these new standards.

Wouldn't you agree?

Administrator BROWNER. I think it is important to think about this in the real world, and what the science now shows us is that far too many people under current levels of pollution are experiencing aggravated asthma. They are having more attacks. We make the decision and we propose the decision based on the science and the recognition that too many people are suffering and that the law requires a level of public health protection.

I mean, I don't think anyone—and I don't want to say that you're suggesting this—but I don't think anyone would find it acceptable for us to sort of say, "OK, for the children out there who are experiencing asthma attacks because of polluted air, aggravated asthma attacks, don't go outside, or hold your breath when you walk home." I mean, that is not a solution. I mean, we have to look at where the science takes us, and the science shows that a lot of people, a lot of people, do experience effects.

It also—when you propose to strengthen the standards, when you propose to tighten the standards, it is also important—and I would

be the first to admit this—to recognize that we continue to preserve the health of some number of children. I mean, we can't ignore the fact that some number of healthy children will without taking action become ill and preventing them from becoming ill in the first instance has always been part of what the Clean Air Act envisioned.

Senator SESSIONS. I just want to try to get a little more clarity in what we're talking about.

We know that ozone has been falling because of regulations this government has imposed consistently for a long time. We also know that asthma attacks are going up, and we don't know why that is true. It is certainly not because ozone is increasing. There is something else that is causing the increase in asthma attacks of which we don't know, and that to me points out some of the problem.

All this 122 million figure says is that is how many people live in areas that are now under these new standards. It can be nothing else, the way I would calculate it.

Another thing on the standards and science of it, again, I'm not a scientist. The commissions have studied it, but I notice that Dr. Schwartz of Harvard, who supports your standards, the first line virtually in his statement to the committee was that on the proposed particulate standard the EPA is not out in front on the science and lags behind the rest of the world in data on that.

Would you agree with that?

Administrator BROWNER. I have not seen that particular statement. I would be more than happy to take a look at it.

Senator SESSIONS. This is what he said.

The EPA is not out in front of the science on the proposed particulate standards, but rather lags behind a number of governments in Western Europe and international scientific bodies.

Administrator BROWNER. What my colleagues who were at the hearing say Dr. Schwartz was saying is that the EPA and the United States lags behind in terms of the public health protections that other places have tighter standards.

Senator SESSIONS. I'm reading his written statement. It says, "The EPA is not out in front of the science on the proposed particulate standards."

Administrator BROWNER. As I hear you say that, what he is saying is we haven't gone beyond where the science takes us, but we are following where the science takes us, which is what the law requires of us, best current science. I mean, we can, obviously, all check with him, but my sense is what he is saying, based on what you are reading is that the EPA is following the science, which is what we are required to do.

Senator SESSIONS. Well, I just think when we know a new period is coming up, a new 5-year report and analysis has to be made, the EPA does need to be out in front in developing and ensuring that scientific research is done so that when we get to that point, we can make the most rational decisions that are possible.

Administrator BROWNER. That is why, obviously, the scientific work is ongoing and why, as I think Senator Inhofe noted, the EPA budget does include dollars for ongoing scientific analysis. That would be appropriate.

[The prepared statement of Senator Sessions follows:]

STATEMENT OF THE HON. JEFF B. SESSIONS, U.S. SENATOR FROM THE
STATE OF ALABAMA

I would like to thank Senator Chafee for holding this hearing today to discuss the EPA's proposed changes to the Ozone and Particulate matter standards. I would also like to thank EPA administrator Carol Browner for appearing before this committee and to express my commendation to all who have done so much to identify and help solve air pollution problems. In partnership with cities, states and industry, we have seen the national levels of both ozone and particulate matter decrease significantly in recent years.

We hear many arguments on both sides of the issue concerning the increased health benefits, or lack thereof, for families and children. As a father of three, I want to find an answer to this health problem and support those parents and dedicated health professionals who are working for the cleanest possible air. However, the recent hearing held before the Clean Air subcommittee with a panel of scientists who advise the EPA, raise questions as to whether the proposed new standards for ozone and particulate matter will be the best way to better health.

Testimony from that hearing showed that the proposed new ozone standard will have only a minimal impact on the number of hospital admissions, leaving the bulk of those who suffer still looking for an answer.

Testimony from that hearing also illustrated a lack of scientific data to support proposed changes to the particulate matter standards.

In addition, dialogue from that hearing served to demonstrate the disagreement within the scientific community regarding changes to those standards, relative to the health merits such a change might bring. One study on particulate matter conducted by Dr. Joel Schwartz of Harvard University, in Birmingham, Alabama, showed that an increase in PM concentrations adversely affected health and caused increased premature death among those who were elderly or had serious health problems. However, a study by Davis and Jackson, of the National Institute of Statistical Science, using the same data, noted that when you added one more factor, humidity—the causality between mortality and increased levels of particulate matter became “statistically insignificant”—casting serious doubt as to whether or not particulate matter or some other factor may have been at play.

Certainly, there appears to be no clear consensus from the scientific community regarding the benefits of imposing these standards. Dr. Morton Lippmann, former chairman, and the current chairman of the EPA's Clean Air Scientific Advisory Committee, Dr. George Wolff, both expressed serious disagreement over the science used as the basis for establishing new standards for particulate matter and ozone. One issue they did seem to agree upon however, was the need for the scientific community to have more time to collect and analyze data, and to weigh the health benefits such changes may or may not bring. Further, Dr. Schwartz, who testified in favor of the new standards, flatly stated that the EPA “lags behind” in the scientific analysis of this issue.

The EPA is currently working under a court order to complete its review of particulate matter standards. As the former Attorney General for the State of Alabama, I have witnessed many instances when groups have filed lawsuits and used court orders a tool to help push through their agenda. It is important to note that the court order does not require the EPA to consider ozone standards but only to review the current standard for particulate matter. It does not require the Agency to impose new standards.

In conclusion, I am in support of policy decisions based on sound science which will have a positive health impact on the families and children of this nation. If we are unsure about what is causing the increase in respiratory ailments, and the science appears to be inconclusive, then let's direct our efforts into promptly conducting the studies that will give us that information—then act.

Thank you, Mr. Chairman, for this opportunity to learn more about how and why these new standards have been proposed. I look forward to learning more about this issue from today's witnesses.

Senator CHAFEE. Thank you, Senator Sessions.
Senator Smith.

**OPENING STATEMENT OF HON. ROBERT SMITH, U.S. SENATOR
FROM THE STATE OF NEW HAMPSHIRE**

Senator SMITH. Thank you, Mr. Chairman.

Good morning, Administrator BROWNER. I have a statement that I would like to enter into the record, Mr. Chairman, and beyond that, I would just make a comment.

I heard your comments regarding the backyard barbecues on the way into work this morning. I heard an ad that certain members of the Senate and the House were willingly rolling back—willingly wanting to roll back standards for clean air so that children could get sick. So I think I am just as outraged by that ad, whoever ran it. I don't even remember who it was.

Administrator BROWNER. I would agree.

Senator SMITH. I just want to ask one question for clarification on the Executive Summary, National Air Quality and Emissions Trends Report.

Administrator BROWNER. It is our Trends Report, I believe?

Senator SMITH. Right, and in that report there is a chart that lists each of the six items, and it says, "air quality percent change." This is from 1986 to 1995. "Carbon monoxide minus 37 percent, lead minus 78, nitrogen oxygen minus 14, ozone minus 6, PM₁₀ minus 22, and sulphur dioxide minus 37."

We still have not reached full attainment on the 1990 Act. Is that correct?

Administrator BROWNER. The States have adopted their implementation plans. They are putting—the plans are there that bring us into attainment and the steps are being taken. Similarly, we have worked with industry to develop the new technologies, the new solutions, and those are now being installed.

It is true from the time you make a decision, from the time you adopt a plan and you develop a technology, there is then a period of time that plays out for the implementation.

Senator SMITH. Do we have any idea once it's fully implemented how much those numbers would change? I would assume they would go up slightly if the Act were to be fully implemented.

Administrator BROWNER. I'm trying to remember that particular chart. That chart may well be what the public health protections, the current public health standards for the six most commonly pollutants get you when full implementation is achieved. I apologize—I can go back and look at that chart.

Senator SMITH. All right, if it is—let's assume for the sake of argument that it is full implementation. Does that figure remain—if we didn't do anything except maintain the current standards, let's say, if we made no changes, we just stayed where we are, do those figures remain static or do they change?

Administrator BROWNER. They can change. Whether or not they will change we will only know at the time. Obviously, you have changes in the economy, you have changes in different industrial sectors, so you can have changes in terms of the gross numbers.

It might be helpful, Senator, for me to just explain one thing for a moment. The law very specifically told the EPA to focus on the six most commonly found air pollutants—those are the six you read. You might want to know that in the last 4 years we did our 5-year reviews not just on particulate and ozone, but we also did them on carbon monoxide, sulphur dioxide and nitrogen dioxide, and in all of those we retained the current standards on.

Senator SMITH. My point is that is a good track record. That is a very positive statement for what the Clean Air Act has accomplished. My question is simply do those figures remain constant or will they change if you didn't do anything except maintain where we are? If we looked at this 5 years from now, would ozone be minus six or would it be minus 11? I mean, does anyone have any idea?

Administrator BROWNER. I think they essentially stay the same. Here is the trouble we're having—

Senator SMITH. I want to ask one question—

Administrator BROWNER.—one growth does occur but technology continues to improve. So you get some increase because of growth but you get a decrease because of technology. They will remain essentially the same, and our requirement is to make sure that if keeping them the same is adequately protecting the public's health. What we found in most instances is yes; in two we found no.

Senator SMITH. One final question regarding the northeast. As you know, there are certain areas of the country that are in non-compliance, in many cases through no fault of their own or not entirely through their own fault.

I'm concerned that more stringent standards could leave an area like the Northeast in non-compliance for even longer periods of time, which is beyond our capability to correct. Are these standards going to enhance that problem?

Administrator BROWNER. I think in fact it is the opposite, which is a more stringent public health standard reduces overall pollution which is better for your State and for many other States. If we take the steps to reduce the generation of pollution based on protecting the health of the American people, it will be better particularly, I think, for your State.

Senator SMITH. Except for the fact in a State like New Hampshire if we drove all electric cars, we still couldn't keep in compliance.

Administrator BROWNER. Well, one of the things that we have learned over the last 20 years in implementing the Clean Air Act is that much air pollution is really a regional phenomenon, and, for example, we have a process underway—your State is engaged in it and many of the States here are in fact engaged in looking at how to deal with the regional problems, recognizing that you cannot simply address this on a State-by-State basis. Some of your pollution may in fact be coming from somewhere else.

Senator SMITH. My time is up, but when you are in non-attainment—the point is when you are in non-attainment, you are in non-attainment, and you are expected to get into the attainment category, and you may not be able to do it, and I respect what you are trying to do and say on the other areas where the causes of the problems are whether it be, you know, the midwest or wherever. But the point is if these standards are stacked on top of the others in the areas of non-attainment where we cannot do anything about it really, that complicates the problem for those regions.

Administrator BROWNER. What strengthening or tightening the standard would do is in fact require those other areas to do their fair share and thereby improve the quality of your citizen's air.

I want to say something more generally about ozone. If you look at the areas that today might not be able to meet a tougher standard, the standard we've proposed, 70 percent of those areas would be able to meet a tougher standard through currently available or about to be available solutions.

Let me explain what I mean. Cleaner gasoline is being used in many cities to reduce air pollution. It could be used in more cities. It's available; we don't need to do anything else. It's been designed and it's being sold. Next year because of some very good work done by Mary Nichols and her colleagues in the Air Office, the cars that are sold in this country will have a little \$10 device inside. You won't even know it's there. It's called an on board canister and it reduces air pollution. As more and more cars are sold with this new air pollution device, the pollution levels come down. So if you look at those sorts of things—and we have many more of these cleaner small engines, cleaner diesel engines, cleaner train engines, they're in the pipeline and they're coming. There are technologies that are being developed, are developed, about to be implemented.

When you take into account just what we know, not what our minds can dream of, but what we know, 70 percent of the areas that might not today meet a tougher public health standard would be able to do so through available common sense cost-effective solutions.

[The prepared statement of Senator Smith follows:]

STATEMENT OF HON. BOB SMITH, U.S. SENATOR FROM THE STATE OF
NEW HAMPSHIRE

Thank you, Mr. Chairman, for holding this hearing today on what is certainly a complex and controversial issue—EPA's proposal to tighten the ozone and particulate matter standards under the Clean Air Act.

I believe it is incumbent upon this committee and Congress as a whole to carefully and thoughtfully examine this far-reaching proposal to ensure that sound scientific principles have been adhered to, and that the entire scope of costs and benefits has been evaluated. I'm interested in seeing that we adopt good public policy, not expedient public policy. I care deeply about protecting human health, but we must consider the full ramifications of our actions.

From the subcommittee hearing last week, there was consensus that the Clean Air Scientific Advisory Committee did not have adequate time to deliberate; that another 5 years would be needed to develop adequate data on fine particles; and that the court-ordered deadline perhaps forced premature recommendations. Of course, we need to be concerned about the health effects of these air pollutants and we are taking steps now to reduce them. But, we must ensure that any tightening of these standards is done using sound science.

While much of southern New Hampshire does not currently meet air quality standards of ozone, a significant portion of the ozone problem in this part of New Hampshire is due to the transport of air pollutants from outside the state. New Hampshire's utilities have made great strides in reducing emissions within the state and reformulated gasoline has been introduced in our non-attainment areas, but it's still not enough. Consequently, I have been a strong supporter of taking steps to improve New Hampshire's air quality by addressing the air transport problem using cost-effective, market-based approaches.

While EPA's proposal is only in draft stage and these standards are not due to be finalized until this Summer, I am concerned about the potential for new non-attainment areas to be created as a result of these standards, particularly since much of New Hampshire's air problems come from outside our borders.

I am also concerned, like Senator Chafee, that this standard setting process could produce a backlash against the Clean Air Act. EPA recently produced the Clean Air Trends Report that clearly shows what great progress we are making in cleaning up the air in this country—and we will continue to make progress even in absence of these standards. For example, the acid rain reduction program is just getting into high gear. The trends report shows a 37 percent reduction in sulfur dioxide and that

means a 37 percent reduction in particulate matter since sulfur dioxide is converted to fine particles.

In conclusion, Mr. Chairman, we must proceed carefully with regard to the new standards. It is important to remember that every solution creates new problems so we need to ensure that the public health is protected in the best way possible—not the most expedient and popular way possible. We only need to recall the asbestos fiasco a number of years ago when Congress mandated that asbestos be removed from schools only to find out later that we had released more asbestos into the air and exposed more children to it, while costing school districts millions in removal and remediation costs. In short, we made a mistake and had to come back and fix it. I don't want that to happen with these rules.

Thank you, Mr. Chairman, and I look forward to hearing Administrator Browner's testimony and the opportunity to ask questions.

Senator CHAFEE. Thank you, Senator.
Senator Hutchinson.

**OPENING STATEMENT OF HON. TIM HUTCHINSON,
U.S. SENATOR FROM THE STATE OF ARKANSAS**

Senator HUTCHINSON. Thank you, Mr. Chairman.

Administrator Browner, with all due respect and great appreciate for the conviction and the sincerity and passion with which you've made, I sincerely question the certainty that these new proposed air standards—based upon what we heard last week in the hearing from scientists, based upon my own study and reading, the certainty that these new proposed standards are following best science, I think that certainty and that dogmatism is greatly exaggerated.

But I want to pick up on one phrase you've used. In one of your answers you said, "The practicality of attaining these standards." So let me just make a few points, and then I'll ask you to respond.

I understand that during CASAC's deliberations several members indicated that there was a need to mandate the collection of monitoring data that would allow for a better characterization of PM_{2.5}. There is relatively little information regarding actual levels of PM_{2.5}. In fact, the EPA's criteria document states, and I'm quoting, "No credible supporting toxicological data are yet available for PM_{2.5}." There are thousands of monitors that measure PM₁₀ because that is the current standard that States have to live by to be in attainment, but there are relatively few monitors in the United States that have the ability to measure PM_{2.5}.

As I understand the EPA's PM_{2.5} proposal—I can see new charts coming up immediately—the new 2.5 proposal would set new annual average and 24-hour average standards based on a 3-year rolling average of these values in an area. If I am correct in my understanding, it would take about 5 years before States could realistically determine non-attainment areas. I say 5 years because there are currently no monitoring networks for PM_{2.5}. They would have to be developed—could take up to a year. Once the monitoring begins, enough data must be collected to determine non-attainment.

Because the EPA has proposed standards involving 3-year averages, at least 3 years worth of data would be necessary to determine which areas are non-attainment. Then after these 3 years the data would have to go through a quality control process, which is required by the EPA and may take about a year to ensure that all the readings are valid.

So we have a 4- to 5-year time period before adequate data would be available on $PM_{2.5}$. However, it would seem that the Governors would have to submit a list of non-attainment areas at about the same time that they would just be getting a monitoring network fully operational.

According to the Clean Air Act, 1 year after the EPA sets the clean air standard Governors must submit a list of non-attainment areas in their States. Two to 3 years after the standard is promulgated, the EPA must designate non-attainment areas based on those submitted lists.

Administrator BROWNER. OK, now—

Senator HUTCHINSON. Let me—I've been waiting a long time for my 5 minutes.

Once the State is designated non-attainment, the State must submit a State implementation plan in 3 years showing how it will attain the standard. But here is the point—if you compare the time line required by the law under the Clean Air Act and the realistic time line to determine non-attainment areas for $PM_{2.5}$, there seems to be a conflict between the availability of data on ambient $PM_{2.5}$ concentrations and the rigorous legal deadlines that are set in the Clean Air Act.

Now I have a series of questions while the light is still green. How can the Governors make valid judgments about an area's non-attainment status without 3-years of valid $PM_{2.5}$ data?

Administrator BROWNER. They are—

Senator HUTCHINSON. Let me finish.

Administrator BROWNER. Oh, I'm sorry. Do you want me to respond as you go along?

Senator HUTCHINSON. Let me finish.

Administrator BROWNER. I've got to write them down. Hold on.

Senator HUTCHINSON. How can they make valid judgments about an area's non-attainment status without having the 3-year's valid $PM_{2.5}$ data? How can they possibly provide meaningful lists of areas for non-attainment designation 1 year after you promulgate $PM_{2.5}$ standard when no monitoring network or ambient data exist for $PM_{2.5}$ today? And have any regulations or guidance been developed for setting up such a network, given that $PM_{2.5}$ differs from PM_{10} , obviously?

So to me it looks like a long time to do the monitoring. Wouldn't it be appropriate to wait until we have that data to make that kind of imposition upon the Governors?

I'm done.

Administrator BROWNER. You have done a great summary of a very lengthy portion of the Clean Air Act, and let me try and step back for just a moment, if I might.

I think there are two questions here. First, did we have—did the scientific community have 2.5 information when they did their health effect studies? That's one question, and then the second question is what has to happen—what are the steps, as you very nicely set out—that flow from a public health decision in terms of implementation, in terms of monitoring networks?

Let me begin with did the scientists have the 2.5 information? What we have up here, Mr. Chairman, and members of the com-

mittee, is a map of all the cities in the United States where 2.5 is being measured.

Senator HUTCHINSON. How many is that? Is that less than 50?

Administrator BROWNER. It's 51 cities where—

Senator HUTCHINSON. 51 as opposed to thousands.

Administrator BROWNER. If I might just—the point is, and I'm speaking to the first question, there is a lot of data about what happens when people breathe 2.5 particles. That's what this shows, that there is 2.5 being measured.

Now in terms of developing and implementation programs, you are exactly right. The EPA will set guidelines in terms of what is the monitoring network. In fact, we are now taking comment on what is called a Federal Referenced Method, and just like we do for lead, like we do for ozone, like we do for PM₁₀, an entire network will be put in place, as it should be.

Based then on that network, which we anticipate we can get up and running in the timeframe envisioned by the Clean Air Act, Governors, based on the facts that they receive—

Senator HUTCHINSON. How long is that?

Administrator BROWNER. We're starting now, actually. The work is being started now.

Senator HUTCHINSON. Will it take a year to get the network up?

Administrator BROWNER. What the law envisions, just to make this clear, is that a Governor not have to make a final set of decisions without the network. I think that's the question you're going to.

Senator HUTCHINSON. It's more than that. Is there an estimate of how long it will take to get the monitoring network up?

Administrator BROWNER. It takes—about 2 to 3 years.

Senator HUTCHINSON. Two to 3 years.

Senator CHAFEE. Now, folks, we are running over a bit here. If you can answer Senator Hutchinson's question, and then we'll move on.

Administrator BROWNER. It takes about 2 to 3 years to fully install the network, and we are beginning the process now.

Senator CHAFEE. Did you have a balance of a question that he asked that you have not answered?

Administrator BROWNER. Yes, but—

Senator HUTCHINSON. Mr. Chairman, I just want to say I think if you look at the time line as to what you're going to be requiring of the Governors, and what the requirements of the Clean Air Act are, there is a big conflict in what they're going to be able to do practically.

Administrator BROWNER. If we might respond, this is a very detailed question for the record with specificity. If I might say, there is a long history under the Clean Air Act of how this relationship and public health standards and the work of the EPA and the States evolved, and no Governor would be required to do anything until he or she had the appropriate data base. That is what the Federal Referenced Method gives you, and that is what we are now working on.

[The prepared statement of Senator Hutchinson follows:]

STATEMENT OF HON. TIM HUTCHISON, U.S. SENATOR FROM THE STATE OF ARKANSAS

Thank you, Mr. Chairman. I am, once again extremely pleased to have this hearing today. The more I understand about this issue, the more I realize there is to learn.

Last week at the science hearing, I learned how much difference in opinion there is, even among the CASAC scientists, regarding the findings of CASAC and what should be done about those findings.

It is obvious how difficult and complex these issues are to understand, but the fact that there was such division among the scientists was very surprising. One of the points you continuously stressed in your testimony during the Arizona court case was the need for time to do studies so that you could make "scientifically sound" decisions for PM_{2.5}.

I completely agree and I am sure there is nobody in the United States who doesn't want these studies to be based on sound scientific principles. If we are going to implement these standards, it is important to understand the science behind the problem so we can eliminate the problem.

Unfortunately, based on the fact that there is very little data on PM_{2.5}, it does not seem that your decision is based on science that is scientifically sound. It seems that your decision was based more on pressure to make a decision than on sound scientific principles. I look forward to your response on this issue.

Regarding ozone, I am alarmed by a couple studies that indicate that there is a possibility that, even if we eliminate all man-made Volatile Organic Compounds (VOCs), some areas of the country could never be in attainment.

Another concern I have is the fact that there is no scientific evidence that supports a threshold level for regulation of ozone. In other words, we do not know if there is any level, including the naturally occurring background level, that ozone is safe.

I am concerned with the fact that I have heard claims that ozone causes asthma, yet we heard from Dr. Thurston and others last week that this is not the case. Ozone simply does not cause asthma, yet these scare tactics have sent fear throughout the United States.

I am interested in the truth behind the problem of air pollution. I want to know that we are doing the right thing that will save lives, yet there seems to be little in the science that supports these standards.

Sure, there are scientists that will support these standards, but there are scientists, even scientists on CASAC, the committee EPA appoints to study ozone, that will dispute these claims.

We need to know all the facts before making such a huge decision. I know we all are interested in learning all the facts in the science, as well as the facts in the decision. For these reasons I look forward to this hearing.

Thank you Mr. Chairman.

Senator CHAFEE. Thank you.

Thank you, Senator.

Senator Lautenberg.

**OPENING STATEMENT OF HON. FRANK R. LAUTENBERG,
U.S. SENATOR FROM THE STATE OF NEW JERSEY**

Senator LAUTENBERG. Thank you, Mr. Chairman, and I apologize to the Administrator for not having here through her testimony. I hope that what I'm going to ask about hasn't already been discussed.

There is an EPA study that suggests the benefits of air pollution controls far outweigh the costs. The study reveals that for every dollar that is spent on pollution controls since 1970, the country has gained \$45 in health and environmental benefits, and, of course, that includes doctor's visits, hospitalization, work time lost.

If we tighten the standards that we're now talking about, can you see it yielding similar benefits, similar cost-effectiveness?

Administrator BROWNER. When we look at the two standards taken together in terms of the public health protections that they will provide, the cost of meeting those standards, what we find is

on balance the benefits will exceed the cost, as has been the history under the Clean Air Act.

Senator LAUTENBERG. Are we talking about similar proportions?

Administrator BROWNER. The range is not as large as the historical range, but I would like to caution—

Senator LAUTENBERG. It need not be, of course.

Administrator BROWNER. Well, I think it is important to just explain to people when you do a cost benefit at this point in the process, there is a speculative nature to it. Until you actually sit down industry-by-industry and figure out exactly which one can most cost effectively be used to reduce how much pollution, you're dealing with ranges, and they can be fairly broad ranges.

Once we complete a public health phase, we then move into an implementation phase, which can make a more precise judgment in terms of cost and benefits, as the law requires.

Senator LAUTENBERG. Now because part of what we are required to answer is the industrial response—it says, you know, the cost far outweighs any benefits, etcetera—and I don't know how that argument ever really gets solved until there is a historical performance to judge it by. So I would hope that we can establish the fact that the costs, though dispersed among lots of people, lots of places, can be easily justified if we are willing to take the risk with some of these, or at least develop as much information as we can to make the case.

Administrator BROWNER. That is certainly what our cost-benefit analysis now shows. It is 10 to 20 times greater in terms of the benefits exceeding the cost.

Senator LAUTENBERG. And, again, if you've discussed this, please let me know. The existing Clean Air Act, did you discuss in your testimony why it is that these aren't really competitive decisions, that one need not render the clean air less effective if we proceed with the new standards for ozone and PM?

Administrator BROWNER. I spoke briefly to the Clean Air Act. I might add that I believe, and I think many people believe, that the public health requirement of the Clean Air Act, which has been a part of the law now for 25 years, was one of the most important steps taken by this Nation, and it has resulted in dramatic improvements in our air quality and it gives us a framework to continue the task, to make sure that we're providing the public health protections to the American people.

Senator LAUTENBERG. It seems to me that there is—I would use the word assault, but that perhaps is a little enraging so I won't use that word—but there is a challenge to the fact that you've linked PM and the ozone standard together.

What are the benefits by addressing both of these at one time?

Administrator BROWNER. Well, I think it is, one, important to understand that many of the sources of the pollution will be identical, that it is the same sources that generate ozone problems, the same sources that generate the fine particle problem. So by working these two standards together, these public health protections, it will allow us in the implementation phase to find the more cost-effective solutions to work with industries so they have to make one round of adjustments, not two rounds of adjustments.

I think it is also important to understand that the health effects can be similar, that while they are separate pollutants, separate sometimes precursors, they can in fact result in very similar health effects. So in terms of what it is that we seek to do for the American people, managing them together makes a lot of sense.

Finally, I might point out that while everyone is aware of the fact and makes reference to the fact that we are subject to litigation in the case of the fine particles, there was in fact litigation on ozone. And, as we explained to the American people in a Federal Register notice 4 years ago now, that we avoided a court-imposed deadline because we promised—in a Federal Register notice we promised a Federal judge that we would get the job of ozone done by mid-1997. There is a whole notice laid out and the steps we would go through, and what the judge in that case said to the litigants who wanted the judge to impose an order is,

The government has come forward. They are owning up to their responsibility. They are making a public commitment. I'm going to allow them to hold to their word, but, quite frankly, if they engage in unreasonable delay, you, the litigant, have every right to come back to me.

We made a promise to the American people, and we want to honor that.

Senator LAUTENBERG. Thanks, Mr. Chairman.

[The prepared statement of Senator Lautenberg follows:]

STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM THE STATE OF
NEW JERSEY

Thank you, Chairman Chafee. I want to welcome Administrator Browner to our hearing, and to commend you for your outstanding leadership at the Environmental Protection Agency. We are all fortunate that you will be staying on in President Clinton's second term.

We are here today to discuss the EPA's proposed rule for ozone and fine particulate matter.

My views on this, Mr. Chairman, are colored by the air that overhangs my state. New Jersey has a real problem with air pollution. In fact, all but two counties already fail to comply with existing standards. New Jerseyans therefore have a special interest in making sure that we do everything possible to improve air quality.

My views on the proposed rule also are shaped by my deep concerns about the serious health consequences of air pollution.

Ozone is a major problem in my state. And there seems to be a strong correlation between high ozone levels and asthma. Emergency room visits for asthma in Central New Jersey occurred 28 percent more frequently when ozone levels were above 60 parts per million. And I would note that 60 parts per million is only half of the current standard.

EPA is proposing to strengthen that standard, and there are sound health reasons to do so. Some critics of EPA's proposal recognize that the present standard is insufficient to protect many of those who work or exercise outdoors. But some of these same critics are resisting tougher standards. Instead, incredibly, they propose that Americans simply spend more time indoors when ozone levels increase.

It's the ostrich approach to air pollution. But it makes no sense for humans.

Let me point out that EPA's proposed rule is supported not only by environmentalists. It's also strongly supported by the largest utility in my state. Like many companies in the Northeast, this utility has invested substantial sums to comply with present ozone rules. Yet its competitors in other states have not. Meanwhile, pollution from those other states regularly drifts into the Northeast. The end result is not only dirty air in New Jersey, but an uneven playing field that puts Northeastern businesses at a significant competitive disadvantage.

I also want to emphasize that as we evaluate EPA's proposed standards, the real question should be whether the proposals are sufficient to protect public health with an adequate margin of safety. The purpose of these standards is to establish the levels above which public health is threatened. They only set a goal. And EPA's proposal would give states time to reach that goal.

The establishment of these goals should be made without regard to the costs of implementation. After all, we're talking about protecting our families and our children from serious health consequences. And who among us is ready to put a price on the life of a child?

Having said that, EPA's proposal does not ignore the financial implications of tougher standards. To the contrary, we can adjust implementation schedules, if compliance is economically impractical.

But the question before us today is not how long those schedules should be. The question is what standard is needed to protect our children. And when it comes to protecting children, in my view, we cannot and must not compromise.

Again, I want to thank Administrator Browner for her leadership, and I look forward to hearing her testimony.

Senator CHAFEE. Thank you, Senator.
Senator Bond.

**OPENING STATEMENT OF HON. CHRISTOPHER S. BOND,
U.S. SENATOR FROM THE STATE OF MISSOURI**

Senator BOND. Thank you, Mr. Chairman.

Madam Administrator, last year in the appropriations process in which you and I engaged at your request I included \$18.8 million for research on particulate matter. We were advised that scientists have concluded that the current data did not adequately demonstrate causality or provide sufficient information to establish a specific new control strategy.

I would like to know what you have been able to do with that \$18.8 million and what results you have.

Administrator BROWNER. We are in fact using that money—it was money we requested to help us better understand how to make the decisions that flow from the public health standards, and, if I might ask Dr. Huggett to explain some of the specifics.

Mr. HUGGETT. With the money appropriated in 1997, we have research going on in mechanism and dose. We have research going on for better methods in epidemiology. In the exposure area we have exposure modeling work going on. We have exposure assessment research—

Senator BOND. Excuse me, Madam Administrator. There is an ongoing study. You, obviously—you have not received the final results. Is that correct? I trust that you will advise this committee and the appropriating committee, but, basically, you do not have the final details on it.

I believe there were some questions asked earlier, Madam Administrator, about something called the Small Business Regulatory Enforcement Fairness Act. You will recall that that not only passed the Small Business Committee unanimously, but it passed the Senate unanimously and was adopted without dissent in the House and signed into law by the President.

Now some time ago the former ranking member of the Small Business Committee, Dale Bumpers, and I wrote to you personally as Administrator to ask about your compliance with the provisions in that law and the Regulatory Flexibility Act in the promulgation of the new NAAQS.

I have today received a letter dated February 11, signed by an Assistant Administrator For Air And Radiation. In that letter I think the operative point is, "In a nutshell, we believe that the proposed NAAQS," N-A-A-Q-S, "are not susceptible to regulatory flexibility analysis, as prescribed by the RFA because the NAAQS do

not impose regulatory requirements on small entities. Instead, State plans implementing the NAAQS establish State regulations that may apply to small entities.”

Now, we wrote to you—this is the Assistant Administrator. Is this your answer? Is this the position that you take?

Administrator BROWNER. Yes.

Senator BOND. Now are you familiar with the Regulatory Flexibility Act?

Administrator BROWNER. Yes, I am.

Senator BOND. You notice in section 603 it says that “such analysis shall describe the impact of the proposed rule on small entities.”

Now, are you and Ms. Nichols telling us that there are no impacts on small entities from this?

Administrator BROWNER. We are in a public health phase of the Clean Air Act. We are doing the outreach to small business, which I think is envisioned by this law, which we support.

In terms of the detailed regulatory analysis, that can only flow once we actually move into the implementation phase because it is there that you begin to really understand which precise businesses might have to take steps. To do it now would be to do it at a very, very gross level, quite frankly, without the kinds of specificity that I think the law rightly envisioned. It is absolutely positively something that we think is important. It is something we will do, and we are not ignoring the intent of the law in terms of working with small businesses. That has begun, that is ongoing.

Senator BOND. Madam Administrator, excuse me. Before my time expires, I have to say that I believe you are ignoring the letter of the law by claiming there is no impact. You’re saying that if I went out bear hunting and pointed a gun and pulled the trigger at a bear and the bear fell dead, it would be the bullet that had the impact on the bear. And you would say that I, pointing the gun and pulling the trigger, had no impact.

I believe that that is just dead wrong.

I would like to submit for the record, and, Ms. Browner, for your response a letter from Senator Domenici, which states in essence if this in fact is the EPA’s position, I can tell you unequivocally that the EPA is simply wrong.

[The letter follows:]

PETE V. DOMENICI
NEW MEXICO

United States Senate
WASHINGTON, DC 20510-3101

COMMITTEES:
BUDGET
APPROPRIATIONS
ENERGY AND NATURAL
RESOURCES
INDIAN AFFAIRS
GOVERNMENTAL AFFAIRS

February 6, 1997

Carol M. Browner
Administrator
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Administrator Browner:

I am writing with regard to EPA's recently proposed National Ambient Air Quality Standards for ozone and particulate matter. Specifically, I am concerned that in issuing those proposed standards EPA may have failed to comply with the Small Business Regulatory Enforcement Fairness Act (SBREFA).

As you know, in 1996 Congress passed, and the President signed, SBREFA to bring a long-overdue measure of regulatory fairness to America's small business community. As you are also aware, Section 244 of SBREFA requires the establishment of small business advocacy review panels to give small businesses an opportunity to express their views on impending EPA regulations.

However, it is my understanding that no small business review panel was convened prior to EPA's publication of the proposed ozone and PM rules. Just as troubling is a published report by the *Environmental and Energy Study Institute's Weekly Bulletin* (February 3, 1997) in which EPA's press officer is quoted as saying that the reason no small business panels were convened is because they are not required before proposing a rule, only before implementing it.

If this is in fact EPA's position, Administrator Browner, I can tell you unequivocally that EPA is simply wrong. I authored the bill that was ultimately included in SBREFA as Section 244, and Section 244 is clear that small business review panels must be convened prior to a rule's proposal. I was equally explicit about this requirement in my floor statement during debate on the measure.

Indeed, convening small business panels prior to a rule's proposal is the entire point of Section 244. In developing the review panel requirement, I was guided by the recommendations of a five-agency forum on small business held in 1994. That forum, which included EPA, specifically identified "[t]he need for more small business involvement in the regulatory development process, particularly during the analytic, risk assessment and preliminary drafting stages."

Moreover, EPA itself has previously recognized that small business advocacy review panels must be convened before a rule is proposed. In his April 2, 1996 memo on implementing the requirements of SBREFA, EPA's General Counsel wrote that "the agency must undertake *prior to proposal* a prescribed small entity stakeholder process" as required by Section 244 (emphasis in original). Consequently, I was troubled to learn that EPA then apparently failed to follow SBREFA's requirements when it proposed the ozone and particulate matter standards.

Let me make clear that this is not an issue about the Clean Air Act, which you and I both recognize is a vital tool in protecting public health. Rather, this is an issue about EPA following federal law in developing its regulations. In passing and signing SBREFA, Congress and the President carefully considered the most appropriate ways to give America's small business men and women a voice in the federal regulatory process.

I appreciate your most timely attention to this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,



Pete V. Domenici
United States Senator

I authored the bill that was ultimately included in CERCLA. I would also include statements by the Governor of Missouri who says to move the target at this point would upset a fragile coalition and would have immense consequences. There are many other letters, which I will submit for the record which outline the extreme distress that the State Governor in Missouri and local officials, mayors and others have because the EPA has not gone through the process established by law. I would expect that while you make good faith efforts to talk to small business, there are specific requirements that must be followed that you have not followed.

Administrator BROWNER. As we complete this process and begin the complicated implementation phase, we couldn't agree with you more for the need to do this kind of analysis. I mean, maybe I could go back to your analogy of the bear. The problem, quite frankly, right now is we don't know which bear and we won't know that until we move into the implementation phase, and then we have to analyze bear by bear.

[Laughter.]

Senator BOND. We say that before you pick out a bear, there are certain responsibilities.

Administrator BROWNER. We agree. That's what we're saying—we agree.

Senator BOND. You haven't—you've already set it in motion.

Administrator BROWNER. Yes, but—

Senator CHAFEE. All right, all right. My father once told me to never argue with analogies.

[Laughter.]

Senator CHAFEE. Now we're going to go another round, and I'm delighted that some of the Senators are still here.

Madam Administrator, this is not a dispute over costs, and you keep coming back to that, but as far as I'm concerned, it isn't. I've been involved in the 20 years that I've been on this committee with every major environmental law that there is—clean air, clean water, endangered species, the CFCs, you name them, and drinking water. And you are absolutely right that the dire predictions about costs have not been realized and that the programs came in at less than that.

But what this discussion is about, as far as I am concerned, is effectiveness, and I don't think it is adequate to just say we can't consider anything except health. If a proposal causes great difficulty with minor improvements, which I believe your ozone proposal does, then I think we ought to proceed with caution and a few alternatives. Clearly, the control of particulates from your own testimony, whether you take the Lung Association at 60,000 lives extended or you take your own at 40,000, is, I believe, the correct way to go especially since we haven't even met in great sections of the country the 1990 standards on ozone.

I would like to pursue that a little bit, if you might. In my State if we closed all businesses down and did nothing but farming, we would still be in non-attainment, and you recognize that and these plans to achieve the attainment under the 1990 Act were due in 1994. As the deadline approached, many areas couldn't make it so then you created or there was created the Ozone Transport Assessment Group, the so-called OTAG, and that was meant to come up

with the solution to this problem. They have been working since May 1995. Recently, their work has fallen behind in schedule, and so now what is your answer to our problem?

Now, on top of all of this, you tighten up the standards when we in the East—and I can just speak particularly of my own State—on even meeting the 1990 standards, and your OTAG Group seems to be falling apart.

Administrator BROWNER. Well, in fact, I think OTAG is something that has great potential, has begun to deliver on that potential.

Senator CHAFEE. We hope it has, 37 States.

Administrator BROWNER. Thirty-seven States. It is not easy. It is not easy to bring together a diverse range of views, to sit in a room, and, quite frankly, do what we've all been talking about here, which is find the cost-effective common sense solution. That is what they're doing—they're prioritizing what are the steps to reduce the air pollution and recognizing, and I think this is particularly true, Mr. Chairman, for your State, that the lion's share of your problem may not in fact originate in your State. It is coming from somewhere else, and other people will have to take a series of actions not only to improve their air quality but to improve the air quality of the people of Rhode Island, the people of Connecticut and other Northeast States.

You, I think, make an extremely good point with respect to the particle standard, the proposal we make there. Those are very real, unfortunately, permanent effects. It is death that we are talking about—20,000, 40,000, 60,000—those are large numbers of people whose lives are cut short because of certain levels of pollution.

In the case of ozone, we're not talking about death, but I think we would all agree for the child who experiences asthma, who can't play outdoors, for the individual who works outdoors and can't go to work on a particular day, for that individual those are equally troubling health effects. It is not death, but it is no less troubling.

Senator CHAFEE. Madam Administrator, let's concede all of that, but the problem is we're not even meeting the 1990 standards, and on top of this, you pile another layer which isn't going to be met, and I hardly think that increases the respect of the law.

Administrator BROWNER. While it is true that we are still working in a number of areas to reduce pollution to meet the current health standards, it is also true that every single thing that is being done in any community by any industry to reduce pollution would be done, would be important to be done, even if you tighten the standards. It doesn't change. You're building—it's a set of building blocks, and what we are doing now is putting in place a layer that give us one level of protection. What the science shows us is that's not adequate so we'll have to add another block. It is not without its challenges. I'm the first to admit that.

Senator CHAFEE. Well, that is not really quite accurate. My time is up, and I'll just be very brief here. You're saying, "Don't worry, that we'll add new standards but in your attempt to achieve the old standards, you're really working toward achieving the new standards too."

Administrator BROWNER. Correct.

Senator CHAFEE. The States are required to submit the so-called State Implementation Plans, SIPS, and in that the delete a series of—and with great trouble in arriving at these SIPS, in devising them they go through a lot of trouble.

Now what you're saying is, "Well, that is not going to do the trick. The SIPS are fine. They might achieve the 1990 standards, but forget them," I presume you're saying.

Administrator BROWNER. No, we're not saying that. Mr. Chairman, that is not what we're saying at all. We have—the EPA has invested a huge amount of effort and energy in developing these SIPS, as have States and local governments, as has industry. No one is suggesting that any step that has been taken or is about to be taken is a step that shouldn't be taken. It is all contributing to cleaner air. The science now shows us we need another step on top of, not in place of, but on top of.

Senator CHAFEE. Senator Baucus.

Senator BAUCUS. Thank you, Mr. Chairman.

Administrator, obviously, these proposed regulations raise lots of questions. Could you outline for us please the various steps along the way before a company, a person, an industry, small business would actually feel the effects of any proposed regulations? I mean, first of all, we're in a comment period, which means there could be adjustments, and changes, and negotiations. You get new data, new information. Then there is a different period of time within which I think you get data. Then there is another period of time involved with the SIPS.

Could you just outline for all of us the different steps and what can be done and what considerations or what adjustments, if any, can be made during each of the steps before an entity actually feels the effects of this?

Administrator BROWNER. I think it is fair to say that it is a very lengthy process. It involves large numbers of parties with all of the safeguards envisioned in any administrative process in terms of public comment, rulemaking—

Senator BAUCUS. Could you outline what they are? Could you outline each step?

Administrator BROWNER. In the case of—there are two ways generally that we will improve air quality. One is through national standards on industry, particular industries.

Senator BAUCUS. I'm talking about these regulations.

Administrator BROWNER. There are two things that will flow from the public health standards. One is work with large industries, businesses across the country and a set of standards to reduce their pollution.

Anything we do with respect to any individual industry, with respect to any type of any sector of the economy, business, all of that is subject to cost benefit with public review and comment, to propose standards with public review and comment, and it is a many year process. It would be our strong hope that some industries, as they have done before, will come to the table and sit with us in formulating that. That is one phase.

Senator BAUCUS. Yes, but correct me if I'm wrong because we don't have much time here, but essentially, first of all, there is a period within which you would take comments for the final regula-

tion, and the final regulation could be different from the post regulation?

Administrator BROWNER. Yes, correct.

Senator BAUCUS. All of us should keep that in mind. It could be different; it may not be the same.

Administrator BROWNER. It could be.

Senator BAUCUS. Second, as I understand it, the EPA then over a period of time—I think it is a couple or 3 years—collects data and tries to determine which areas may or may not be in attainment. Is that correct?

Administrator BROWNER. That is a separate—that is the other side of the equation, which is we work on parallel tracks. One with businesses, industry; the other is working with States and local government to develop the additional tools, the additional steps they will take. That is also a many, many year process with public comment.

Senator BAUCUS. Right, roughly how many years? Roughly, how many years?

Ms. NICHOLS. In the case of ozone, if the standard is changed in June 1997, the EPA would designate roughly 2 years after that, State plans would be due 3 years after that. In 2002 the initial attainment date for the revised standard under the current law is 5 years after designation, so that takes you to 2004. There is an extension possible based on the severity of the problem and availability of control measures, which gets you to 2010, and potentially to 2011, if there is an additional 1-year extension.

Administrator BROWNER. And that's for the State plans, just to be clear.

Senator BAUCUS. Correct, and I understand it, State plans then can be very complex, very different visions for different entities. It's your point that one size should not fit all.

Administrator BROWNER. Right.

Senator BAUCUS. So there is time within which to work this out.

Administrator BROWNER. There will be huge debate, I don't doubt, about each component.

Senator BAUCUS. And during the time not only health effects in sum total, but also the cost considerations are very significantly considered. It's a balance, basically, in many respects.

I know this point has been made before, I think, in my absence, but the main point is time after time again whenever cost estimates are made it turns out that the actual cost is much less than the estimated cost.

Administrator BROWNER. Yes.

Senator BAUCUS. One example that comes to my mind is in the Clean Air Act Amendments, particularly SO₂ credits. I mean, we, according to our best judgment, back in 1989 or 1990 thought that it would be \$1,500 per ton. That is my recollection.

Administrator BROWNER. Yes, that is correct.

Senator BAUCUS. You agree—\$1,500 per ton. That was the best estimate of what SO₂ credits would cost.

What does it cost today?

Administrator BROWNER. We're going to show you a chart we actually have. Today on the Chicago Board of Trade you can buy acid rain credit for \$78, and that is per ton.

Senator BAUCUS. Per ton. And has that dropped quickly?

Administrator BROWNER. In fact, it has. The estimates, obviously, date back to the debate, which was more than 10 years ago. In 1990 the EPA had an estimate which was a little bit lower than the industry. It was \$800 to \$400, and today it is \$78.

Actually, since they went on sale it has been roughly in the \$78 range. They went on sale, what, 2 years ago now that they've been for sale. So it did drop rather quickly.

Senator BAUCUS. This may not be accurate, but I was told years ago when the original Clean Air Act was passed, the Congress asked the automobile industry to come up with catalytic converters. The industry said, "No, it can't be done. It is impossible. We don't have catalytic converters. It's too costly and it can't be done."

Congress decided, well, go ahead and make catalytic converters, and my understanding is that not only did we come up with the catalytic converters, but it forced the industry to go back and redesign their exhaust systems and found that after the catalytic converters were designed, the cost of the exhaust systems were actually considerably less than they were in the first place.

Administrator BROWNER. That is absolutely right.

Senator BAUCUS. That doesn't always happen, of course. I'm not saying that is necessarily going to happen here, but I do think it is fair to say that given the imagination and creativity that people have, and because we're basically a bottom line culture—that is, balance sheets and income statements—that people are pretty creative in finding less expensive ways to achieve their goals and their results.

So that is, obviously, why initial costs always overstate the actual costs.

Thank you.

Administrator BROWNER. You're exactly right, Senator Baucus, and I think that is one of the greatest stories of the Clean Air Act over its 25 years is the fact that we have been able to reduce air pollution for far less than we projected, and the benefits have been far greater. We have a study right now on a 20-year period. It is in scientific peer review, and we will release it when that peer review is completed. But what it shows is that the cost of cleaner air over 20 years, that the benefits have exceeded the costs 45 times.

Senator BAUCUS. Is that in the record?

Administrator BROWNER. We will give you that. It is a draft study. As I said, we are in the final phases of peer review. We will go ahead and provide you with the draft, and then when the peer review is completed, obviously, with that document.

Senator BAUCUS. Thank you, Mr. Chairman.

Senator CHAFEE. Thank you, Senator.

Senator Warner.

**OPENING STATEMENT OF HON. JOHN W. WARNER,
U.S. SENATOR FROM THE COMMONWEALTH OF VIRGINIA**

Senator WARNER. Thank you, Mr. Chairman.

Welcome, Madam Administrator. I just want to talk a little bit about philosophy. I have found that the American people want to obey the law—your law, whatever. It seems to me that you're moving ahead to establish public policy and put that into law when you

acknowledge here today that there is going to be 30 percent of the community—several in my State—which cannot under any knowledgeable means today meet the requirements.

So with one hand we're putting the law into effect knowing that 30 percent of the people—that is, 30 percent of the community and the people in those communities—can't meet that law. Somehow to me that is just the wrong way to go about government generally.

As a side bar over here, those communities are anxious to participate in the yearly allocation of highway funds, and there is the question put on their right to get those highway funds because they can't meet the attainment you've established.

That may have well been covered, Mr. Chairman, earlier today, but it's a question that I'm struggling with.

Administrator BROWNER. No, that is a good question. I think it is a very, very appropriate question. If you look at the history of the Clean Air Act, and the chairman himself made a reference to CFCs and chlorofluorocarbons. When the Congress made what was a very bold public health decision to say, "Let's get rid of them," we didn't know what the replacement would be. We didn't know. The science hadn't yet advanced enough to develop a substitute; the technology wasn't there. But industry did rise to the occasion, and they did it for less money and in a shorter period of time than anyone anticipated, and today we in fact are seeing improvements in the upper ozone. The hole is shrinking because of that.

I actually think it is very good news that we could provide more Americans with a level of public health protections, cleaner air—70 percent of the areas through existing technologies—and that the challenge is far smaller than it has been previously under the Clean Air Act. I think the thing that I take my greatest hope from is not just CFCs, or acid rain, or cleaner cars where we've done it, and we've done in less time and more cost effectively, it's the city of Los Angeles.

When I came to my job at the EPA over 4 years ago, there wasn't a plan for the city of Los Angeles to meet public health air standards currently the law. It didn't exist, but we sat down, the city sat down, the State sat down, the businesses sat down, environmentalists sat down, and we have a plan today. If we can do it for Los Angeles, I don't doubt that we can do it for any part of this country and give the American people the benefits of cleaner air. It is not without its challenges, but it is a challenge we have risen to before, and I know we can do it again.

Senator WARNER. Well, that may well be the case. Certainly, we've seen that connection with our automobiles. I think the industry has made some bold accomplishments there.

Administrator BROWNER. Yes.

Senator WARNER. But when you talk about ozone, that is a pretty tough one to deal with, and I have one community—I'm very privileged to have it here in northern Virginia, which is the infrastructure within much of the Federal Government, and if we call took the subway tomorrow, put the cars in the garage and took the subway, and walked across the bridges—it's good exercise—if we all stopped everything, still we can't meet it. To suddenly say to those folks that have been struggling for years, "I know you have differences with my Governor, but we've worked to try, and it's hope-

less. Therefore, you're just going to go ahead and be in violation of the law," and there could be a question of whether or not I can direct some of the highway funds to that community, which desperately funds to try and break the gridlock, the lost hours of waiting for these commuter lines and the like—that's what they're looking for.

Administrator BROWNER. We certainly agree and have been engaged in a process which the chairman referred to with the Northeast States and then expanding to all the States east of the Mississippi with the fact that a lot of the pollution problems, particularly the northeast States are dealing with, they're not generating; that we have to look on a regional basis.

By following the science, strengthening the public health protections and then working to secure the implementation, you will see a set of actions required that not necessarily have to be undertaken by your State, but in other parts of the country that will benefit your air quality. I mean, there's, I think, some amount of fairness here, that some people have done quite a bit and others, quite frankly, have not done enough. What this does is it gives you a mechanism for ensuring that everyone is doing their part for cleaner air, that all industry is honoring their responsibility to reduce their pollution levels.

Senator WARNER. Well, with all due respect, you and I have a different approach as to how to effect important changes in America, whether it's in this area or other areas. But I still continue to adhere to the principle that our citizens want to obey the law. It's the responsibility of the Congress to enact those laws, which they can achieve, and they understand. And, in this instance, I think we fall seriously short.

Thank you, Mr. Chairman.

Senator CHAFEE. Thank you, Senator.

Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

Administrator Browner, Senator Warner's statement frames the choice we have, it seems to me, and it frames it in this way. Incidentally, when it comes to obeying the law, you're obeying the law. The law orders you to come before us and do exactly what you're doing today, which is to tell us what we have to do to achieve clean air that protects people's health with an adequate margin of safety.

Now Senator Warner raises an interesting and important question. Why would we want to promulgate a standard that we know that 30 percent of the communities in his State can't meet? Well, what's the choice? The choice is to hold back and not tell them what we think science says will protect their health, and, as you've said over and over again today, there is a second phase to this, and that is the implementation phase and that's where 30 percent of the Virginians—and we've already it, as I've said in Fairfield County. The EPA gave Fairfield County 17 years to meet the standard in that part of Connecticut.

I should follow Senator Chafee's warning about analogies, but I can't resist letting Senator Bond's bear sleep in the woods, if I might say so myself.

[Laughter.]

Senator LIEBERMAN. What we're talking about at this phase with your order might be a regulation describing how the gun is manufactured, or maybe some general rules about hunting. In the next phase we're going to do some studies about what the hunter is likely to shoot at, and whether there are any bears in those woods that are going to be endangered.

I worked very closely with Senator Bond on the Small Business Fairness Enforcement Act. It's an important piece of legislation, and you can't tell us now—you're dealing with health here. You're not dealing with what is going to be required to achieve it in the second phase. You'll get to the flexibility with 30 percent of the communities in Virginia and with small business.

Second, Senator Smith referred to the ads about kids suffering and the ads about people not being able to barbecue. We're all around here experienced enough to know that people can overstate on either side of an issue.

However, there is a difference here. It seems to me that you've got science-based statistics that suggest that kids' health will be affected by dirty air if change is not made. As far as I know—and this is the momentous question I want to ask you—the order you are proposing will not prohibit me or any other American from barbecuing if it goes into effect or of mowing our lawn?

Administrator BROWNER. You are free to barbecue. You are free to mow your lawn, and, moreover, to enjoy the 4th of July fireworks.

Senator LIEBERMAN. OK, I presume that that does not mean that you are not in negotiations or conversations with people who are in the business of manufacturing products for barbecuing or lawn mowing to try to encourage them to do it in a way that is less adverse to our health.

Administrator BROWNER. Well, in fact, we have had a very successful project with small engine manufacturers, everything from the little engines people use on their fishing boats to lawn mowers, and we have through an agreed process been able to reach a design for a cleaner, small engine that is extremely important in terms of air quality. And people today can go to their local hardware store and buy a cleaner, small engine lawn mower.

Senator LIEBERMAN. Let me come to the ozone standards because we've talked a lot about this, and this is important. I do want to say, again, and I'm going to not use the word respectfully because I got chastised for it, although I do want to say to the chairman that I will respect him even as the morning ends. I still do respect the chairman, notwithstanding his request that I not state that respect.

Whether or not the old standards are being adhered to or met is not the question that the statute forces you to report to us. It is what is the best health right now.

Administrator BROWNER. Correct.

Senator LIEBERMAN. The numbers on the chart are a big confusing, and they may have overstated it, but as I look at it, I look at the children protected, and you're telling us that 13 million more children will be protected under the proposed standard; that three million more asthmatics will be protected, and that three million more people with respiratory diseases will be protected.

Now that is 19 million people. That's not any small subgroup of super-sensitive people. That's a lot of people and a lot of families being protected.

On the question of what's an adverse health effect, how did EPA determine, for instance in the case of ozone, what constitutes an adverse health effect? There's been a certain sense here that you're being a little bit—you're reaching too far. I mean, as one of our colleagues said at one point, "You know, if a child is out there and maybe they're asthmatic, they ought not to be out there on certain days of the year."

Is that what we're talking about?

Administrator BROWNER. The studies for ozone cover—there are a variety of different scientific studies that are done, including putting people in what are called inhalation chambers and having them breathe polluted air at a whole variety of levels and then measuring the health effects.

Senator LIEBERMAN. These are normal kids or kids with asthma?

Administrator BROWNER. They're healthy people. You put them in a chamber, and they breathe polluted air. Obviously, we don't do this where death is an issue. No scientist is going to find somebody—

Senator LIEBERMAN. A good decision.

[Laughter.]

Administrator BROWNER. But in the case of ozone, there are a set of inhalation studies that have been done from .09, to .08, .07, .06, on down, and then you measure the health effects, and then what you see when you display all of the studies, including the inhalation, is that by proposing a .08 8-hour standard, the number of health effects you can protect against.

Senator LIEBERMAN. Thank you.

Senator CHAFEE. Senator Warner.

Senator WARNER. I should be very brief, Mr. Chairman.

When we talk about projection, 30 percent of the communities will be in non-attainment. Under other calculations, it's a far higher number of communities, and I'm just going to read you an example.

For example, in Albany, NY, MSA, there are six counties. Only three of these six counties have monitors, so EPA predicts that of the three counties two will be proposed new standing and one county will not.

Administrator BROWNER. Senator, if you might just help me understand. Are you speaking to ozone or fine particle?

Senator WARNER. We're talking about the proposed .08. That's what—

Administrator BROWNER. OK, I just want to make sure I understood because there are two different issues.

Senator WARNER. Sure.

So how are you treating these MSA's? That's what I'm talking about.

Administrator BROWNER. The question—

Senator WARNER. In other words, it looks like only 30 percent, when in reality, I think I can show you some calculations that's much higher than 30 percent.

Administrator BROWNER. If I might just step back and explain how this portion of the law works in sort of real life.

Under the Clean Air Act, lines are drawn on maps around areas and then decisions are made as to whether or not the air within that area is meeting a public health standard. That is what the MSA refers to. For a variety of reasons, we have now learned that how you draw those lines should perhaps be different. An example would be in an urban area, you have large numbers of people driving in every day. They live in a suburban area, but they're contributing to the urban population. So when you want to develop solutions to reduce the pollution, you don't look just small, but you look more broadly.

We are suggesting and we are taking comments on changing how you draw the lines. The most important reason being that we think that would give greater flexibility to local and State governments to find better solutions. It is better based on our current knowledge of how pollution actually operates, and so what would happen is there would be the need in some areas because you would change how you draw the line to more accurately reflect how pollution operates to add some monitoring stations. That could very well be required, and that can be easily done.

Senator WARNER. Well, you're counting the greater metropolitan Washington area as one of the 30 percent. To me that's wrong because you've got at least—

Administrator BROWNER. No, we're not. That's not how we're doing that.

Senator WARNER. The law requires the non-attainment areas to be measured according to the MSA.

Administrator BROWNER. Right, and because of our recognition that the MSAs may not have been the best mechanism to allow you to find the common sense pollution solutions, we are taking comments on whether or not that should be adjusted.

Senator WARNER. Well, this is the list, I think, under your structure of 30 percent, so to speak—

Administrator BROWNER. I don't know what list that is.

Senator WARNER. This is the EPA Projected Ozone Non-Attainment Cities In 2007. My point is I think you can run a calculation where there is a lot higher number. Thirty percent is something I take respectfully—that's it, and what you're doing is not just isolating only 30 percent over here, but it is a much higher number.

Administrator BROWNER. If it would be helpful, we would be more than happy to provide for the record the analysis we did that brings us to that statement. That might be helpful.

Senator WARNER. I thank you.

Administrator BROWNER. Thank you.

Senator CHAFEE. Thank you, Senator Warner.

I've just got a couple of more questions. Do the other Senators have questions?

[No response.]

Senator CHAFEE. You have chosen .08 for your ozone standard. Yet, at .07 you would achieve better results, and I suppose you could go right down to the background levels, which are, what, something like .04 or .05.

So you've portrayed the position you've taken as one of looking after the health of children and others, and, yet, why didn't you go down to .07?

Administrator BROWNER. Because when we looked at the science, what we saw in terms of sort of the real world studies, the camp kids studies, the hospital admission studies, is that the health effects and the health effects you would want to protect against can be—that you can do that at .08.

I have to say in addition to those scientific studies, in addition to the fact that that is where the science took us, equally important to me is the fact that on the independent peer review panel, the four medical health experts, three of them said .08 and the fourth one said .08 to .09. They specifically discussed these issues of .07, .08, .09, and we have health studies at .06—

Senator CHAFEE. I think they also said it's a policy judgment. Am I correct?

Administrator BROWNER. It is, as any decision we make, a decision that has to be informed by the science, by the evidence, and this is where the science took me. That is true. The science took me—

Senator CHAFEE. In other words, we don't have the so-called bright line that we had—well, when we were doing the CFCs, for example. Step over this line and when you've reached this line, you've now achieved a protection of health. You go over it, and you won't achieve anything more. That's not the situation here. You've chosen the .08, but it could be .07, and, as we've mentioned, it probably could go right down to background levels.

Administrator BROWNER. I mean, I think it is a hard comparison to make. There is no natural background level for chlorofluorocarbons. That is a man-made chemical that is being put into air.

I mean, it is true and it has been recognized—in fact, Senator Muskie spoke very eloquently during the debate on the 1977 amendments to the issue of no bright line, no threshold. I mean, it has been recognized in this work for decades now that there are natural background levels of ozone, and there may very well be some small number of people who do experience some small number of effects, even at a background level.

The .08 that we propose and that we take comment on is where the science took us in terms of the health effects that we thought were the most troubling, that the medical experts thought were the most troubling, that we should be protecting against.

Senator CHAFEE. Final question, as I've indicated here, I think where you're going to do your real achievements is on the particulates and the 2.5, which I applaud you for choosing. I'm worried about the monitoring stations, and this gets back to Mr. Huggett.

The cost of installing those I think the—how many were going to be required across the country?

Administrator BROWNER. Actually, this is not Dr. Huggett's issue. This would actually be the Air Office issue. Why don't I have her explain how these monitoring systems are put in place, and we have them already for a lot of other pollutants. So this is something we're very familiar with.

Senator CHAFEE. But I think these are quite different, as I understand these monitoring ones for the particulates, but go ahead, Ms. Nichols.

Ms. NICHOLS. I would just say that we put out for proposal at the same time we put out the ozone and particulate matter standard proposals a proposed PM monitoring regulation. The structure of the program is that the EPA approves the monitoring system. We approve a reference method, and then we approve a plan for deploying the monitoring devices.

It is a phased plan that is being proposed here. This year we're actually beginning the deploying of the first 70 monitoring stations around the country.

Senator CHAFEE. How many do you envision across the country?

Ms. NICHOLS. Ultimately, we will probably end up with several hundred monitoring stations. There is still some debate about the exact number in places.

Senator CHAFEE. That's what I thought. I'm informed that there are 1,400 PM₁₀ stations, but this would, obviously, be for a finer particle than the PM₁₀'s.

So, in any event, I hope you get on with that, and if you require more money, I hope—obviously, this is something where the States are going to require some assistance—I would hope you would include that in your budget and make a real effort for it.

Ms. NICHOLS. We would agree.

Senator CHAFEE. I think that is what Senator Bond was talking about when he gave you that money last year. It was for this.

Administrator BROWNER. That is correct.

Senator CHAFEE. Any other questions.

Senator BAUCUS. Madam Administrator, you said it's the science that led you to the policy decision of .08.

What is it in the science that led you to that conclusion?

Administrator BROWNER. It's the number of people whose health are affected. It's the number of aggravated asthma, respiratory illnesses. It's the fact that far too many people when the pollution is at that level are experiencing real effects.

Senator BAUCUS. But, again, at a tighter standard more would be protected.

Administrator BROWNER. Right, and by tightening the standard, as we propose to do, we would be providing protection to 133 million Americans.

Senator BAUCUS. Why not .07?

Administrator BROWNER. When you look at the science, when the health experts looked at the science, they felt that .08 gave the level of protection that the law envisioned, that that is where the science took them.

Senator BAUCUS. Doesn't it really get no more to the point that, as you said earlier, there is no bright line, and that we're talking here not about exact science but about sound science?

Administrator BROWNER. I think—

Senator BAUCUS. That, as I understand it, the number of people affected from .08 to .07 is much less than the number of people affected from .09 to .08.

The main point I'm trying to make here is that when we talk about science, we're talking about sound science. We're not talking

about perfect science or exact science. We're trying to do the best we can in making some judgment calls here because there is no perfect science in these areas.

Administrator BROWNER. Well, science continues to move on. I think what is—

Senator BAUCUS. There are differences of opinions and views.

Administrator BROWNER. There will always be differences of opinions. I think what is very important here—

Senator BAUCUS. People look at different data. When they conduct experiments, data sometimes happens to be different.

Administrator BROWNER. Well, that is why you have a CASAC process. That is why the law directed us to engage in a public review of the science.

In closing, if I might just say, Senator Baucus, Mr. Chairman, 250 plus peer reviewed scientific published studies—that is clear and convincing. I believe it is compelling. We have never had anything of this magnitude when it comes to making a public health decision for the people of this country.

Senator BAUCUS. What you're saying is this is a study much more extensively than other standards?

Administrator BROWNER. Absolutely. We've never had—

Senator BAUCUS. How much more? Can you quantify it?

Administrator BROWNER. You know, we could go through sort of proposal by proposal—

Senator BAUCUS. Ten percent more, 10 times more?

Administrator BROWNER. In some instances, it could be 10, 20, 30 times more, quite frankly. You have more than 10 years of scientific study that shapes the proposal we make. It is where the science takes us; it is overwhelming.

Thank you.

Senator CHAFEE. Well, that maybe also, Madam Administrator, but when you got to the final cut, as it were, the top review, the big leaguers, if you would, the CASAC Group, they weren't—they didn't have unanimity. I consider unanimity—they had 19 members and in some they had 17 out of 19. That is pretty darn good. I'm not going to argue with that, but there are other ones where they couldn't agree on the period, for example, with the particulates whether it be annual, or daily, or they couldn't agree on the level. So they were all over the lot—

Senator BAUCUS. Mr. Chairman, with ozone they did agree on the range because that is a policy decision.

Administrator BROWNER. Yes.

Senator BAUCUS. They did agree.

Senator CHAFEE. That's right, on the range they did agree.

Senator BAUCUS. Also on particulates they agreed that the standards should be separate—of what it should be.

Senator CHAFEE. That's right, but my point is that you've got a stack of studies this high, peer reviewed, splendid, but when the final peer review—that's what CASAC is—comes in, there was wide disagreement.

Administrator BROWNER. With all due respect—

Senator CHAFEE. That's going to be the motto of this hearing.

[Laughter.]

Administrator BROWNER. I have to say that anytime you can get 19 of 21 scientists, that is huge, No. 1.

Senator CHAFEE. I conceded that. I didn't argue.

Administrator BROWNER. No. 2, when three of four health experts can all agree on .08, that is huge. It is rare that we have that kind of scientific agreement when we make decisions. What we have here is a process, and a body of scientists that, I think, is compelling and leads us to propose to strengthen these standards for the American people.

Senator CHAFEE. OK, fine. Thank you very much, Madam Administrator.

Now if Ms. Katzen can come up, who has waited patiently, or maybe impatiently, we'll take your testimony.

STATEMENT OF SALLY KATZEN, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC

Administrator Katzen. Thank you very much, Mr. Chairman, and members of the committee.

I am pleased to be here this morning. I found it quite illuminating to sit through this morning's discussion of the EPA's proposal to revise the ozone and particulate matter ambient air quality standards. As has been commented on a number of times today, these proposals have sparked extraordinary interest from a wide variety of affected groups—environmentalists and health professionals, who view these standards as a necessary and important step to improving air quality; State and local governments, who have the front line responsibility for implementing these standards; and industry and other entities who will have to take the steps necessary so that areas will comply with whatever standards are adopted.

The interests and concerns that have been expressed range from the health effects to be ameliorated by these standards and the scientific support and other scientific policy issues underlying these standards, to the administrative and other practical means by which these standards will be implemented, to the economic effects in complying with these standards, including the costs that will be incurred as people change their conduct to implement them.

Questions have also been raised about OMB's review of these proposed rules, focusing particularly on the logistics of how and when OMB carried out its responsibilities.

I am here today because it is my office that is responsible under Executive Order 12866 for reviewing executive branch regulatory proposals, and we in fact did review the EPA proposals that are the subject of this morning's hearing.

This morning the EPA Administrator presented extensive testimony and answered a wide range of questions about the Agency's basis for the proposed standards. The Agency should take the lead, for it has the statutory authority and bears the responsibility for developing substantive regulatory standards. Executive Order 12866 specifically recognizes the primacy of Federal agencies in the regulatory decisionmaking process.

OMB's role under the Executive order is to provide dispassionate, objective review of the Agency's work. Our task is to ensure that

the regulatory agency asks the right questions, considers the relevant scientific and other data, employs sound analysis, and balances the competing concerns in a reasonable, practical way.

In addition, for proposed rules—and the rules under discussion today are proposed rules—it is important that the regulatory agency present its proposal and justification for it in a way that assures informed, meaningful input from the public.

Executive Order 12866 sets forth a number of principles generally applicable to regulatory decisionmaking. The Executive order was, however, purposefully qualified to apply—and I am quoting—“to the extent permitted by law.” That qualification is particularly important in this case. As has been mentioned many times this morning, under the Clean Air Act, the EPA Administrator is to set air quality standards that protect public health with an adequate margin of safety. It is a health-based determination, and the EPA Administrator is not to consider economic factors at this stage of the rulemaking proceeding.

Now, having said this, Executive Order 12866 nonetheless requires agencies to prepare economic analyses for proposed and final rules, and to submit them to OMB for review even if economic considerations are not the determinant factor, or even a secondary or tertiary factor. Where, here, a statute prohibits the consideration of economic factors, such analysis is still important because it helps inform the Administration, the Congress, and most importantly, the American people of the benefits and the costs of regulatory activity.

In fact, as has been mentioned this morning, the EPA prepared extensive cost-benefit analyses—over 3 inches of materials—which accompanied the proposed standards when we received them at OMB. We thought it was particularly important that the EPA prepare these economic analyses even at the standard-setting stage. For while the standards are health-based and may not reflect economic considerations, they are not self-executing. Instead, the EPA must follow these standards with regulations to implement them, and in this implementation phase, as Administrator Browner has said, costs should, and will, play a very significant role. Preparing the benefit cost analyses during the standard-setting phase will ensure that those addressing the implementation phase—the EPA, its Advisory Committees, the State and local governments who are responsible for implementing these standards—have the best information possible as they set about their work.

Let me now briefly mention the specifics of OMB’s review of these proposed standards, and, hopefully, touch on the questions that have been raised.

First, before we received the proposed rules, our staff attended a number of meetings at which the EPA explained in general terms the methodology it was using in its analysis of these rules—the data it was relying on, the assumptions and models used. In addition, the EPA and my office hosted a number of interagency meetings with the EPA staff to brief other Federal agencies on the general issues that the EPA would be considering in this rulemaking process.

Second, the EPA submitted the package of proposals to OMB on November 4, 1996. We had to work quickly because of a court-

ordered deadline of November 29, 1996. This put a strain on both my office and the EPA staff as we went about our work.

During these 3 weeks, I know that my staff worked intensely, often late into the evenings and on weekends. We gave this matter top priority, putting aside or postponing temporarily other responsibilities to focus our attention on these standards.

We were able to identify a number of issues that we thought required further work, and while the court-ordered deadline precluded full discussion and resolution of those issues with the EPA, we have been advised by the Agency that some of these issues will in fact be analyzed as part of the economic analyses that will be provided to us as part of the package for our review of the final standards.

At the final rule stage, we will continue our obligations for review of these rules under the Executive order. There are important policy issues that need to be considered, and, as at the proposed stage, we expect that many of the affected parties will want to meet with us and share their views. We welcome those meetings, as it will give us a better idea of the issues on which we should focus as we do our work.

Thank you very much for opportunity to be here and to answer any questions you may have.

Senator CHAFEE. Thank you very much, Ms. Katzen.

I want to take this opportunity to thank you for the excellent testimony you gave maybe just a year ago—against the so-called regulatory reform legislation, which I was very much against and was pleased that it didn't pass, although I'm not sure that it's not still alive out there somewhere. Like Lazarus, it might be back.

I'm curious to know what your review reveals about the feasibility of these standards, and I'm not talking about cost and benefits but whether there are strategies available to meet the standards. My understanding is that the cost estimates couldn't be completed because measures that would attain the standards couldn't be identified.

Am I correct in that?

Administrator Katzen. I would put it slightly differently. We do not do our own estimate. What we do is review the EPA's estimates of the benefits and the costs. The EPA benefit-cost analysis was based on known strategies and technology, to avoid speculation.

As you heard this morning in testimony regarding the timetable, it may be many years before these standards will actually have to be implemented, and there may well be technological breakthroughs that would lower the costs, but we don't know that now. It would be equally difficult to speculate on where bringing into compliance would be on the current cost curve, assuming there are no technological breakthroughs, because such an assumption would be inconsistent with past experience.

So what the EPA did in this instance was look at the areas of the country—locality by locality—to determine, based on known strategies and technology, the costs. This produced what we have in the cost-benefit analysis here. What was missing was the residual non-attainment areas where, based on known technology, they could not now say what the cost would be of reaching full attainment.

This is one of the areas on which the EPA is doing more work as we proceed toward the final rule stage, namely, in looking at the residual non-attainment areas.

Senator CHAFEE. Well, that is a pretty significant section of the country. For example, where I come from is not in attainment.

Administrator Katzen. That is correct, but what the EPA was thinking—and I think Administrator Browner touched on it this morning—is that as part of the implementation phase, they will be looking to the Federal Advisory Committee and the OTAG, which will be recommending, we understand, various strategies that may have a very helpful effect on the air quality in your State by imposing more restraint on areas that are not now subject to existing controls.

With those strategies and policies in place, it then will be possible to determine what the real costs will be, but until they are determined, it is difficult at best to estimate the costs. Such an estimate, if it were simply an extrapolation of the path of the known cost curve, would I think, would be very misleading to the American public about what is at stake here.

Senator CHAFEE. Let's just deal for a moment with the ozone standard.

As I understand it, the EPA has two estimates for the ozone standard. Am I correct in that? One is the so-called local strategy and the other is the regional strategy, which, apparently, is based on a more cost-effective approach.

Am I correct in what I'm saying, and do these cost estimates vary very much?

Administrator Katzen. I can't give you the specific cost estimates specifically of the two different strategies right now. We looked at ranges of costs for both the ozone and the particulate matter standards, and wanted to make sure that they were broken out specifically for each so that we could look at them one at a time.

One of the areas that we want to do further work on is the interrelationship between the two because it will be very important as we look at each of these standards to determine how full compliance with one would affect particulate matter and how full compliance with particulate matter would affect the ozone attainment.

So work on the interrelationship is part and parcel of the work that is being done now and would fit into the types of different strategies that they're looking at.

Senator CHAFEE. OK, well, thank you very much. I'm sorry that you had to wait so long, and, thus, we lost some of our Senators. But we might have follow-up questions, and if you could answer those, we would appreciate it.

Administrator Katzen. I would be happy to answer them to them to the best of my ability.

Senator CHAFEE. Thank you.

Administrator Katzen. Thank you very much.

Senator CHAFEE. I must say trying to use the acronym of your office makes for awkwardness.

Administrator Katzen. I've gotten used to OIRA.

Senator CHAFEE. Where are you from?

Administrator Katzen. I'm from Pittsburgh, PA.

Senator CHAFEE. Oh, I don't mean—

[Laughter.]

Senator CHAFEE. In the Supreme Court the judge asked a lawyer, "How did you get here?" He said, "I came by the Pennsylvania Railroad." He really meant what court did you come up through.

So I'm just—how do you pronounce it? In my State we're blessed with having the Naval Underwater Warfare Center, which is very, very important. It employs some 2,500 civilians and is extremely important, but the acronym of the name is NUWC, which I find a little difficult, N-U-W-C. And you are OIRA, pronounced how?

Administrator Katzen. OIRA.

Senator CHAFEE. OIRA.

Administrator Katzen. OIRA.

Senator CHAFEE. Well, best wishes to everybody down at OIRA and thanks for coming.

[Laughter.]

Administrator Katzen. We need them. Thank you.

Senator CHAFEE. That concludes the hearing.

[Whereupon, at 12:30 p.m., the committee was adjourned, to reconvene at the call of the chair.]

STATEMENT OF CAROL M. BROWNER, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. Chairman, members of the committee, I want to thank you for inviting me to discuss the Environmental Protection Agency's proposed revisions to the national ambient air quality standards for particulate matter and ozone.

On these two pollutants, over the past three and a half years, EPA has conducted one of its most thorough and extensive scientific reviews ever. That review is the basis for the new, more stringent standards for particulate matter and ozone that we have proposed in order to fulfill the mandate of the Clean Air Act.

On average, an adult breathes in about 13,000 liters of air each day. Children breathe in 50 percent more air per pound of body weight than do adults.

For 26 years, the Clean Air Act has promised American adults and American children that they will be protected from the harmful effects of dirty air—based on best available science. Thus far, when you consider how the country has grown since the Act was first passed, it has been a tremendous success. Since 1970, while the U.S. population is up 28 percent, vehicle miles travelled are up 116 percent and the gross domestic product has expanded by 99 percent, emissions of the six major pollutants or their precursors have *dropped* by 29 percent.

The Clinton Administration views protecting public health and the environment as one of its highest priorities. We have prided ourselves on protecting the most vulnerable among us—especially our children—from the harmful effects of pollution. When it comes to the Clean Air Act, I take very seriously the responsibility the Congress gave me to set air quality standards that “protect public health with an adequate margin of safety”—based on the best science available.

Mr. Chairman, the best available, current science tells me that the current standards for particulate matter and ozone are not adequate, and I have therefore proposed new standards that I believe, based on our assessment of the science, are required to protect the health of the American people.

The standard-setting process includes extensive scientific peer review from experts outside of EPA and the Federal Government. Under the law, we are not to take costs into consideration when setting these standards. This has been the case through six Presidential administrations and 14 Congresses, and has been reviewed by the courts. We believe that approach remains appropriate. However, once we revise any given air quality standard, it is both appropriate and, indeed, critical that we work with states, local governments, industry and others to develop the most cost-effective, common-sense strategies and programs possible to meet those new standards.

I want to make it clear that at this point we have only *proposed* revisions to the two standards. We take very seriously our obligation to carefully consider all public comments on these proposals before making a final decision. We want to hear from small businesses, industry, state and local governments, and other citizens like the elderly, children, doctors and people with asthma. While we have proposed specific levels for each pollutant, we are also asking for comment on a wide range of alternative options. I want to assure you here today that I will not make a final decision until comments on all of those alternative options have been carefully considered. EPA went to the court and requested a 60-day extension for the public comment period and the deadline for taking final action on the particulate matter standards. Two days ago, the court granted EPA an extension until March 12, 1997 for the public comment period and until July 19, 1997 for issuing a final decision. We intend to extend the schedule for ozone accordingly.

This morning I would like to describe for you the basis for my recent decisions to propose revisions to the particulate matter and ozone standards. I would also like to discuss some of the innovative approaches we are undertaking to ensure that any newly revised standard would be met in the most cost-effective way possible.

BACKGROUND

The Clean Air Act directs EPA to identify and set national standards for certain air pollutants that cause adverse effects to public health and the environment. EPA has set national air quality standards for six common air pollutants—ground-level ozone (smog), particulate matter (measured as PM₁₀, or particles 10 micrometers or smaller in size), carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide.

For each of these pollutants, EPA sets what are known as “primary standards” to protect public health and “secondary standards” to protect the public welfare, including the environment, crops, vegetation, wildlife, buildings and monuments, visibility, etc.

Under the Clean Air Act, Congress directs EPA to review these standards for each of the six pollutants every 5 years. The purpose of these reviews is to determine

whether the scientific research available since the last review of a standard indicates a need to revise that standard. The ultimate purpose is to ensure that we are continuing to provide adequate protection of public health and the environment. Since EPA originally set the national air quality standards (most were set in 1971), only two of EPA's reviews of these standards have resulted in revised primary standards—in 1979, EPA revised the ozone standard to be less stringent; and in 1987, EPA revised the particulate matter standard to focus on smaller particles (those less than 10 micrometers in diameter), instead of all sizes of suspended particles.

By the early 1990's, thousands of new studies had been published on the effects of ozone and there was an emerging body of epidemiological studies showing significant health effects associated with particulate matter. EPA was sued by the American Lung Association to review and make decisions on both the ozone and particulate matter standards. I directed my staff to conduct accelerated reviews of both standards. In March 1993, I completed a review of the ozone national ambient air quality standards (NAAQS) with my decision *not* to revise the NAAQS, and to accelerate the next review in light of emerging information. Soon afterwards, in February 1994, I issued a *Federal Register* notice committing the Agency to meeting an accelerated schedule for analyzing all of the scientific studies that had become available since EPA completed its last review of the ozone standards. The scientific analysis and review for both pollutants are completed and EPA proposed revisions to the two standards late last year. We expect to announce final decision on both pollutants by July 19, 1997.

I would like to make one final point on this matter. Although the reviews for both the ozone and particulate matter standards have been accelerated, I gave them very high priority and focused the necessary resources on them to ensure that we conducted an exhaustive and open review of the science. The criteria documents alone were six inches thick for particulate matter and three inches thick for ozone. I am satisfied that our decisionmaking process on ozone and particulate matter has been thorough, complete and, as I will describe, based on extensive peer-reviewed science.

EXTENSIVE SCIENTIFIC REVIEW PROCESS USED TO REVIEW THE OZONE AND PARTICULATE MATTER NATIONAL AIR QUALITY STANDARDS

EPA undertakes an extensive scientific and technical assessment process during the standard review for each air pollutant. This includes developing (1) a "criteria document" which reflects the latest scientific knowledge on the kind and extent of all identifiable effects on public health or welfare of the pollutant, and (2) a detailed scientific and technical assessment, known as a "staff paper." Using information in the criteria document, the staff paper arrays a range of policy alternatives based on the scientific evidence and makes recommendations to me. Both of these documents go through extensive public and external scientific peer review.

Our Office of Research and Development is responsible for compiling the "criteria document." These are comprehensive assessments that include thousands of studies that have been published in peer review journals. My Office of Research and Development holds a series of peer review workshops on draft chapters of the criteria document. Once the entire document has been completed in draft form, it is further reviewed by the public and the Clean Air Scientific Advisory Committee, or CASAC.

Established by Congress, the CASAC is a panel of science experts external to EPA. During the review for each air pollutant, the panel is augmented with additional scientific and technical consultants who have expertise related to that pollutant and its effects. In total, there were 21 scientists and technical experts from academia, research institutes, public health organizations and industry who reviewed the particulate matter criteria document and staff paper and 16 who reviewed the ozone criteria document and staff paper. The CASAC reviews were chaired by George Wolff, an atmospheric scientist from General Motors. CASAC meetings are open to the public.

The CASAC panel reviews the draft criteria documents and the key underlying studies and makes recommendations for revisions to the criteria document. Industry, state and local agencies, and other members of the public also submit extensive comments on the draft criteria documents. My staff then revises the document and submits it for another review by the CASAC and the public. This process sometimes repeats itself two or three times until the CASAC sends EPA what is known as a "closure" letter, pronouncing the criteria document as adequate to be used as a basis for a decision on whether or not a given standard should be revised.

Staff in my Office of Air and Radiation also develops a "staff paper." The purpose of the staff paper is to identify the most policy-relevant information contained in the criteria document and the critical elements that the EPA staff believes should be

considered in the review of the standards. The staff paper typically includes quantitative exposure and risk analyses. This document also includes staff recommendations of ranges of alternative standards that should be considered in any decision I may make on revising a standard. Like the criteria document, this draft staff paper is subject to review by the public and the CASAC panel. And like the criteria document, the staff paper often undergoes two or more reviews—where the scientific panel recommends changes and my staff responds to those recommendations—before the CASAC issues a letter of “closure” on it as well. At that point the staff paper, along with the criteria document, is ready for me to use in making my decision as to whether it is appropriate to propose any revisions to the standards.

PUBLIC INVOLVEMENT IN THE OZONE AND PARTICULATE MATTER DECISIONS

Throughout the three and a half year process of developing our proposed standards, we have been committed to analyzing the science in an open public forum and ensuring broad public input. Back in February 1994, we published in the *Federal Register* the schedule we intended to follow for the review of the ozone standard which identified the opportunities for public comment and public meetings.

Each meeting held with the CASAC on criteria documents and staff papers is open to the public. In fact, we have held 11 CASAC meetings totaling more than 124 hours of public discussion on the ozone and particulate matter criteria documents and staff papers. All of these meetings were announced in the *Federal Register* and open to the general public. In addition to the public meetings and the public review and comment on the criteria documents and staff papers, the public has several other opportunities to provide input to a decision on the ozone and particulate matter standard revisions.

In June 1996, EPA published in the *Federal Register* an Advance Notice of Proposed Rulemaking describing the key issues under consideration and timeframes for decisions on the two standards. In July 1996, we held national public meetings in Philadelphia and St. Louis, where we presented these key issues and options we were considering on the two standards and received extensive comments from the public. About 100 representatives of industry, state and local governments, and members of the public people provided comments at those meetings.

In my announcement of the proposed revisions last November, I encouraged broad public participation in the comment process in order to obtain the best information available for determining the appropriate final standards. We have established a virtually unprecedented system for the public to provide their comments. In addition to the normal docketing process for receipt of public comments, we have established a national toll-free telephone hotline (1-888-TELL-EPA) to encourage the broadest amount of public comment possible. Over the past 2 months it has received hundreds of calls from the public. Several key documents have been made available over the Internet. We have also established a system for people to submit their comments via E-mail over the Internet. Again, our goal here is to ensure that we allow for the broadest array of public comment possible.

We also held 2 days of public hearings on the proposed standard revisions in each of three cities—Salt Lake City, Chicago and Boston. In addition, we held a day-long public hearing in Durham, North Carolina on our associated proposal for air quality monitoring for particulate matter. At these hearings, more than 400 citizens and organizations provided testimony about their views of our proposed standards.

We have taken other steps to expand the public discourse on these matters. We have held two national satellite telecasts broadcast around the Nation to answer questions on the standards from officials from state and local governments, industries and other groups. We are also working with the Air and Waste Management Association, a national organization of industry, government and other air pollution control experts, to hold public meetings on the new standards at more than ten different locations. Beyond that, I have instructed my Regional Administrators to hold public forums around the Nation to discuss the issues associated with any possible revision to these air quality standards. My regional office staff are also participating in hearings that states such as California, Texas and Washington are holding on these proposed standard revisions.

In response to requests from a number of interested parties, EPA went to the court and requested an extension of the public comment period and the date for a final decision to provide greater opportunity for public input into these decisions. As I have already mentioned, the court granted us an additional 3 weeks.

RATIONALE FOR EPA'S PROPOSED REVISION OF THE OZONE STANDARDS

Since the mid-1980's, there have been more than 3,000 scientific studies published that are relevant to our understanding of the health and environmental ef-

fects associated with ground-level ozone. These peer-reviewed studies were published in independent scientific journals and included controlled human exposure studies, epidemiological field studies involving millions of people (including studies tracking children in summer camps), and animal toxicological studies. Taken as a whole, the evidence indicates that, at levels below the current standard, ozone affects not only people with impaired respiratory systems, such as asthmatics, but healthy children and adults as well. Indeed, one of the groups most exposed to ozone are children who play outdoors during the summer ozone season.

Certain key studies, for example, showed that some moderately exercising individuals exposed for 6 to 8 hours at levels as low as 0.08 parts per million (ppm) (the current ozone standard is set at 0.12 ppm and focuses on 1-hour exposures) experienced serious health effects such as decreased lung function, respiratory symptoms, and lung inflammation. Other recent studies also provide evidence of an association between elevated ozone levels and increases in hospital admissions. Animal studies demonstrate impairment of lung defense mechanisms and suggest that repeated exposure to ozone over time might lead to permanent structural damage in the lungs, though these effects have not been corroborated in humans.

As a result of these and other studies, EPA's staff paper recommended that the current ozone standard be revised from the current 1-hour form (that focuses on the highest "peak" hour in a given day) to an 8-hour standard (that focuses on the highest 8 hours in a given day). It also recommended setting an 8-hour standard in the range of 0.07 ppm to 0.09 ppm, with multiple exceedances (between one and five per year).

The CASAC panel reviewed the scientific evidence and the EPA staff paper and was unanimous in its support of eliminating the 1-hour standard and replacing it with an 8-hour standard. While I do not base my decisions on the views of any individual CASAC member (as a group they bring a range of expertise to the process), it is instructive to note the views of the individual members on these matters. While ten of the 16 CASAC members who reviewed the ozone staff paper expressed their preferences as to the level of the standard, all believe it is ultimately a policy decision for EPA to make. All ten favored a multiple exceedance form. Three favored a level of 0.08 ppm; one favored a level of either 0.08 or 0.09 ppm; three favored the upper end of the range (0.09 ppm); one favored a 0.09–0.10 range with health advisories when a 0.07 level was forecast to be exceeded; and two just endorsed the range presented by EPA as appropriate.

Consistent with the advice of the CASAC scientists and the EPA staff paper, we proposed a new 8-hour standard at 0.08 ppm, with a form that allows for multiple exceedances, by taking the third highest reading each year and averaging those readings over 3 years. We are asking for comments on a number of alternative options, ranging from 8-hour levels of 0.07 to 0.09 ppm to an option that would retain the existing standard. Just as a point of reference, based on our most recent analysis of children outdoors, when measuring the exposures and risks of concern, as well as the number of areas of the country that would be in "nonattainment" status, the current 1-hour ozone standard of 0.12 ppm is roughly equivalent to a 0.09 ppm 8-hour standard with approximately two to three exceedances.

We considered a number of complex public health factors in reaching the decision on the level and form proposed. The quantitative risk assessments that we performed indicated differences in risk to the public among the various levels within the recommended ranges, but they did not by themselves provide a clear break point for a decision.¹ The risk assessments did, however, point to clear differences among the various standard levels under consideration. These differences indicate that hundreds of thousands of children are not protected under the current standard but would be under EPA's ozone proposal.

Also, consistent with EPA's prior decisions over the years, it was my view that setting an appropriate air quality standard for a pollutant for which there is no discernible threshold means that factors such as the nature and severity of the health effects involved, and the nature and size of the sensitive populations exposed are very important. As a result, I paid particular attention to the health-based concerns reflected in the independent scientific advice and gave great weight to the advice of the health professionals on the CASAC. To me, this is particularly important given the fact that one of the key sensitive populations being protected would be children. The decision to propose at the 0.08 ppm level reflects this, because, though it is in the middle of the range recommended for consideration by CASAC and the EPA staff paper, as a policy choice it reflects the lowest level recommended by indi-

¹ CASAC itself agreed that there are a continuum of effects—even down to background—and that there is no "bright line" distinguishing any of the proposed standards as being significantly more protective of public health.

vidual CASAC panel members and it is the lowest level tested and shown to cause effects in controlled human-exposure health studies.

Finally, air quality comparisons have indicated that meeting a 0.08 ppm, third highest concentration, 8-hour standard (as proposed by EPA) would also likely result in nearly all areas not experiencing days with peak 8-hour concentrations above the upper end of the range (0.09 ppm) referred to in the CASAC and the EPA staff paper. Given the uncertainties associated with this kind of complex health decision, we believe that an appropriate goal is to reduce the number of people exposed to ozone concentrations that are above the highest level recommended by any of the members of the CASAC panel. The form of the standard we proposed (third highest daily maximum 8-hour average) appears to do the best job of meeting that goal, while staying consistent with the advice of the CASAC as a group, as well as the personal views of individual members.

It is also important to note that ozone causes damage to vegetation including:

- interfering with the ability of plants to produce and store food, so that growth, reproduction and overall plant growth are compromised;
- weakening sensitive vegetation, making plants more susceptible to disease, pests, and environmental stresses; and
- reducing yields of economically important crops like soybeans, kidney beans, wheat and cotton.

Nitrogen oxides is one of the key pollutants that causes ozone. Controlling these pollutants also reduces the formation of nitrates that contributes to fish kills and algae blooms in sensitive waterways, such as the Chesapeake Bay.

As part of its review of the ozone science, the CASAC panel unanimously advised that EPA set a secondary standard more stringent than the current standard in order to protect vegetation from the effects of ozone. However, agreement on the level and form of the secondary standard was not reached.

RATIONALE FOR EPA'S PROPOSED REVISION TO THE PARTICULATE MATTER STANDARDS

For particulate matter standard review, EPA assessed hundreds of peer reviewed scientific research studies, including numerous community-based epidemiological studies. Many of these community-based health studies show associations between particulate matter (known as PM) and serious health effects. These include premature death of tens of thousands of elderly people or others with heart and/or respiratory problems each year. Other health effects associated with exposure to particles include aggravation of respiratory and cardiovascular disease, including more frequent and serious attacks of asthma in children. The results of these health effects have been significantly increased numbers of missed work and school days, as well as increased hospital visits, illnesses, and other respiratory problems.

The recent health studies and a large body of atmospheric chemistry and exposure data have focused attention on the need to address the two major subfractions of PM₁₀—“fine” and “coarse” fraction particles—with separate programs to protect public health. The health studies have indicated a need to continue to stay focused on the relatively larger particles or “coarse” fraction that are a significant component of PM₁₀ and are controlled under the current standards. We continue to see adverse health effects from exposures to such coarse particles above the levels of the current standards. As a result, CASAC scientists were unanimous that existing PM₁₀ standards be maintained for the purpose of continuing to control the effects of exposure to coarse particles.

However, a number of the new health and atmospheric science studies have highlighted significant health concerns with regard to the smaller “fine” particles, those at or below 2.5 micrometers in diameter. These particles are so small that several thousand of them could fit on the type-written period at the end of a sentence. In the simplest of terms, fine particles are of health concern because they can remain in the air for long periods both indoors and outdoors contributing to exposures and can easily penetrate and be absorbed in the deepest recesses of the lungs. These fine particles can be formed in the air from sulfur or nitrogen gases that result from fuel combustion and can be transported many hundreds of miles. They can also be emitted directly into the air from sources such as diesel buses and some industrial processes. These fine particles not only cause serious health effects, but they also are a major reason for visibility impairment in the United States in places such as national parks that are valued for their scenic views and recreational opportunities. For example, visibility in the eastern United States should naturally be about 90 miles, but has been reduced to under 25 miles.

EPA analyzed peer-reviewed studies involving more than five and a half million people that directly related effects of “fine” particle concentrations to human health.

For example, one study of premature mortality tracked almost 300,000 people over the age of 30 in 50 U.S. cities.

Based on the health evidence reviewed, the EPA staff paper recommended that EPA consider adding “fine particle” or $PM_{2.5}$ standards, measured both annually and over 24 hours. The staff paper also recommended maintaining the current annual and/or 24-hour PM_{10} standards to protect against coarse fraction exposures, but in a more stable form for the 24-hour standard. This more stable form would be less sensitive to extreme weather conditions.

When CASAC reviewed the staff paper, 19 out of 21 panel members recommended establishment of new standards (daily and/or annual) for $PM_{2.5}$. They also agreed with the retention of the current annual PM_{10} standards and consideration of retention of the 24-hour PM_{10} standard in a more stable form.

Regarding the appropriate levels for $PM_{2.5}$, staff recommended consideration of a range for the 24-hour standard of between 20 and 65 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) and an annual standard to range from 12.5 to 20 $\mu\text{g}/\text{m}^3$. Individual members of CASAC expressed a range of opinions about the levels and averaging times for the standards based on a variety of reasons. Four panel members supported specific ranges or levels within or toward the lower end of the ranges recommended in the EPA staff paper. Seven panel members recommended ranges or levels near, at or above the upper end of the ranges specified in the EPA staff paper. Eight other panel members declined to select a specific range or level.

Consistent with the advice of the EPA staff paper and CASAC scientists, in November last year I proposed adding new standards for $PM_{2.5}$. Specifically, based on public health considerations, I proposed an annual standard of 15 $\mu\text{g}/\text{m}^3$ and a 24-hour standard of 50 $\mu\text{g}/\text{m}^3$. In terms of the relative protection afforded, this proposal is approximately in the lower portion of the ranges or options recommended by those CASAC panel members who chose to express their opinions on specific levels. However, taking into account the form of the standard proposed by EPA, we understand that the proposal would fall into the lower to middle portion of the ranges or options. In order to ensure the broadest possible consideration of alternatives, I also asked for comment on options both more and less protective than the levels I proposed.

Also consistent with the advice of the EPA staff paper and CASAC scientists, I proposed to retain the current annual PM_{10} standard and to retain the current 24-hour PM_{10} standard, but with a more stable form. I also requested comment on whether the addition of a fine particle standard and the maintenance of an annual PM_{10} standard means that we should revoke the current 24-hour PM_{10} standard.

As has been the case throughout the 25-year history of environmental standard setting, uncertainty has played an important role in decisionmaking on the particulate matter standards. Specifically, the uncertainty about the exact mechanism causing the observed health effects has led some to argue that not enough is known to set new or revised standards. In this case, however, because of the strong consistency and coherence across the large number of epidemiological studies conducted in many different locations, the seriousness and magnitude of the health risks, and/or the fundamental differences between “fine” and “coarse” fraction particles, the CASAC scientists and the experts in my Agency clearly believed that “no action” was an inappropriate response. The question then became one of how best to deal with uncertainty—that is, how best to balance the uncertainties with the need to protect public health.

Given the nature and severity of the adverse health effects, I chose to meet the Congressional requirement of providing the public with an “adequate margin of safety,” by proposing $PM_{2.5}$ standards within the ranges recommended in the EPA staff paper and commented upon in the CASAC closure letter. I believe the levels chosen reflect the independent, scientific advice given me about the relationship between the observed adverse health effects and high levels of fine particle pollution. That advice led to a proposed decision toward the lower end of the range of levels for the annual standard which is designed to address widespread exposures and toward the middle of the range for the 24-hour standard, which would serve as a backstop for seasonal or localized effects.

One final note on particulate matter. Some have suggested we need more research before decisions are made about these standards. I strongly support the need for continued scientific research on this and other air pollutants as a high priority. However, as we pursue this research, we must simultaneously take all appropriate steps to protect public health. We believe that tens of thousands of people each year are at risk from fine particles and I believe we need to move ahead with strategies to control these pollutants.

FINDING COMMON SENSE, COST-EFFECTIVE STRATEGIES FOR IMPLEMENTING A REVISED OZONE OR PM STANDARD

Throughout the 25-year history of the Clean Air Act and air quality management in the United States, national ambient air quality standards have been established based on an assessment of the science concerning the effects of air pollution on public health and welfare. Costs of meeting the standards and related factors have never been considered in setting the national ambient air quality standards themselves. As you can see from the description of the process I went through to choose a proposed level on ozone and particulate matter, the focus has been entirely on health, risk, exposure and damage to the environment.

I continue to believe that this is entirely appropriate. Sensitive populations like children, the elderly and asthmatics deserve to be protected from the harmful effects of air pollution. And the American public deserves to know whether the air in its cities and counties is unsafe or not; that question should never be confused with the separate issues of how long it may take or how much it may cost to reduce pollution to safe levels. Indeed, to allow costs and related factors to influence the determination of what levels protect public health would be to mislead the American public in a very fundamental way.

While cost-benefit analysis is a tool that can be helpful in developing strategies to *implement* our nation's air quality standards, we believe it is inappropriate for use to *set* the standards themselves. In many cases, cost-benefit analysis has overstated costs. In addition, many kinds of benefits are virtually impossible to quantify—how do I put a dollar value on reductions in a child's lung function or the premature aging of lungs or increased susceptibility to respiratory infection? Very often I cannot set a value and these types of health benefits are, in effect, counted as zero.

At the same time, both EPA and industry have historically tended to overstate costs of air pollution control programs. In many cases, industry finds cheaper, more innovative ways of meeting standards than anything EPA estimates. For example, during the 1990 debates on the Clean Air Act's acid rain program, industry initially projected the costs of an emission allowance (the authorization to emit one ton of sulfur dioxide) to be approximately \$1,500, while EPA projected those same costs to be \$450 to \$600. Today those allowances are selling for less than \$100.

Another example involves EPA's regulations in the 1970's and 1980's to reduce emissions of smog-forming volatile organic compounds from coating and printing operations. Industry developed powder coatings and ultraviolet light-cured coatings that not only reduced emissions to the EPA-required levels, but essentially eliminated emissions altogether. In addition to saving industry the high cost of equipment for the collection and destruction of volatile organic compounds, these coatings provide for faster production, improved efficiency, reduction in energy costs and frequently improved performance. The coating industry has since developed new export markets. The combination of the Clean Air Act and the European goal of zero emissions of volatile organic compounds is driving the industry to develop new techniques. Although the coating industry as a whole predicts growth of two to 3 percent, the powder and UV-cured coatings are growing much faster to meet the needs of customers to reduce emissions of volatile organic compounds.

On the other hand, the Clean Air Act has always allowed that costs and feasibility of meeting standards be taken into account in devising effective emission control strategies and in setting deadlines for cities and counties to comply with air quality standards. This is certainly the case for any revision we might make to either the ozone or the particulate matter standards. This process has worked well. In fact, our preliminary studies indicate that from 1970 to 1990 implementation of the Act's requirements has resulted in significant monetizable benefits many times the direct costs for that same period.

If we ultimately determine that public health is better served by revising one or both of these standards, the Clean Air Act gives us the responsibility to devise new strategies and deadlines for attaining the revised standards. In doing so, we are determined to develop the most cost-effective, innovative implementation strategies possible, and to ensure a smooth transition from current efforts.

To meet this goal, we have used the Federal Advisory Committee Act to establish a Subcommittee for Ozone, Particulate Matter and Regional Haze Implementation Programs. It is composed of almost sixty members of state and local agencies, industry, small business, environmental groups, other Federal agencies and other groups and includes five working groups comprised of another 100 or so members of these same kinds of organizations.

The Subcommittee and the various workgroups have been meeting regularly for well over a year working to hammer out innovative strategies for EPA to consider in implementing any revised standards. Members from industry, state governments

and others are putting forward position papers advocating innovative ways to meet air quality standards. It is our belief that results from this Subcommittee process will lead us to propose innovative approaches for implementing any new standards. The Subcommittee will continue to meet over the next year to help develop cost-effective, common-sense implementation programs.

The issues being addressed by the Subcommittee include:

- What will be the new deadlines for meeting any new standards? [If EPA tightens a standard, it has the authority to establish deadlines of up to 10 years—with the possibility of additional extensions—beyond the date an area is designated “nonattainment.”]

- What will be the size of the area considered “nonattainment?” If it revises an air quality standard, EPA has the ability to change the size of the affected nonattainment areas and focus control efforts on those areas that are causing the pollution problems, not just the downwind areas that are monitoring unhealthy air.

- How do we address the problem of the pollutants that form ozone and/or fine particles being transported hundreds of miles and contributing to nonattainment problems in downwind areas?

- What kinds of control strategies are appropriate for various nonattainment areas? Can we use the experience of the past several years to target those control strategies that are the most cost-effective?

- How can we promote innovative, market-based air pollution control strategies?

The implementation of these new standards is likely to focus on sources like trucks, buses, power plants and cleaner fuels. In some areas, as with the current standards, our analysis shows that reaching the standards will present substantial challenges. All of the air pollution control programs we are pursuing to meet the current ozone and particulate matter standards, as well as programs to implement other sections of the Clean Air Act, will help meet any revised standards. For example, the sulfur dioxide reductions achieved by the acid rain program will greatly help reduce levels of fine particles, particularly in the eastern United States. Cleaner technology in power plants would also greatly reduce the nitrogen oxides that help form ozone across the eastern United States. In fact, we believe that under certain comprehensive control strategies, more than 70 percent of the counties that could become nonattainment areas under a new ozone standard would be brought back into attainment as a result of a program to reduce nitrogen oxides from power plants and a large number of other sources. Programs under—way to reduce emissions from cars, trucks, and buses will also help meet a revised particulate matter or ozone standard.

I intend to announce our proposals on implementation of the proposed new standards in phases that correspond to the Federal Advisory Committee Act Subcommittee’s schedule for deliberating on various aspects of the program. I expect to propose the first phase of that program at the same time that I announce our final decision on revisions to the ozone and particulate matter standards.

In announcing the proposed ozone and particulate matter standards last November, I directed my Office of Air and Radiation to further expand the membership of the Federal Advisory Subcommittee to include more representation from small business and local governments. Also, in conjunction with the Small Business Administration and the Office of Management and Budget, we are holding meetings with representatives of small businesses and small governments to obtain their input and views on our proposed standards.

There is one last point I would like to make on this matter. Critics of the proposals have been saying that meeting these proposed standards means widespread carpooling and the elimination of backyard barbecues, among other lifestyle changes. The broad national strategy is being developed by EPA, as I have described, with extensive input from industry, small business, state and local governments and others. While the ultimate decisions as to what programs are needed to meet air quality standards are up to the state and local governments, I would like to state categorically that there will *not* be any new Federal mandates eliminating backyard barbecues or requiring carpooling. These kinds of claims are merely scare tactics designed to shift the debate away from the critical, complex public health issues we are attempting to address.

CONCLUSIONS

Mr. Chairman, I commend you for holding these hearings. The issues we are discussing today are critical to the state of the Nation’s public health and environment. It is imperative that the American public understand these important issues. In that regard, I am disappointed that some have chosen to distort this important discussion by raising distracting and misleading pseudo issues like “junk science” and

“banning backyard barbecues.” I am hopeful that this and other hearings and public forums will help focus the national debate on the real health and environmental policy implications of these national air quality standards.

In the Clean Air Act, the Congress has given me the responsibility to review every 5 years the most recent science to determine whether revisions to national air quality standards are warranted. In doing so, the law tells me to protect the public health with an adequate margin of safety.

We are constantly reviewing the science associated with these standards, but we do not often propose revisions to them. I have done so in the case of ozone and particulate matter because of compelling new scientific evidence. For the past three and a half years we have targeted our resources to conduct a thorough, intensive review of this scientific evidence. The scope and depth of this review process has been based on unprecedented external peer review activities.

Given the sensitive populations affected by these pollutants—children, asthmatics, the elderly—as well as possible effects on outdoor workers and other healthy adults, it was my judgment that it was appropriate to propose standards that tended to fall in the lower end of the range of protection supported by my independent science advisors and recommended by experts in my technical offices. Based on the record before the Agency at the time of proposal, including the advice and recommendations of the CASAC panels, I concluded—subject to further consideration based on public comments—that the proposed standards were both necessary and sufficient to protect the public health, including sensitive populations, with an adequate margin of safety.

At the same time, I recognize that the proposed standards involve issues of great complexity and I look forward to receiving a broad range of comments from all affected and interested parties. As I have described, we have gone to unprecedented lengths to provide the public with opportunities to express their views on the proposed standards. We have also expressly requested comments on options (including alternative levels and forms of the standards) that are both more protective and less protective than the levels we proposed.

Mr. Chairman, this concludes my written statement. I will be happy to answer any questions that you might have.

AGGREGATES OF THE MEAN HEALTH RISK ESTIMATES EXPRESSED AS A PERCENT OF OUTDOOR CHILDREN LIVING IN NINE URBAN AREAS EXPERIENCING EFFECTS 1 OR MORE TIMES PER YEAR.

Statistic ^a	Regulatory scenarios				
	1H1EX-124 (new estimates for current 1-hr NAAQS)	1H1EX-120 (previous estimates for current 1-hr NAAQS)	8H3AV-84 (new estimates for 8-hr NAAQS proposal)	8H1EX-80 (previous estimates for 8-hr, 1 expected exceedance standard)	8H5EX-80 (previous estimates for 8-hr, 5 expected exceedance standard)
Estimated Percent of Outdoor Children with Decreased Lung Function (FEV ₁ 15%) 1 or More Times Per Year ^b	7 (3.7-12) ^c	8.3 (4.2-14.2)	5.7 (2.7-10.3)	5.1 (2.2-9.6)	6.7 (3.3-11.9)
Estimated Percent of Outdoor Children with Decreased Lung Function (FEV ₁ 20%) ^b 1 or More Times Per Year	2.6 (1.0-5.7)	3.0 (1.1-6.6)	1.9 (0.7-4.4)	1.4 (0.5-3.7)	2.3 (0.8-5.3)

^a Aggregate of 10-run mean values obtained from applying pNEM/O3 and health risk model to nine urban areas.

^b Effect associated with 8-hr exposures at moderate exertion.

^c 90% credible interval for risk estimates indicated in parentheses.

Percent of Outdoor Children Estimated to Experience Various Health Effects 1 or More Times per Year Associated with 8- and 1-Hour Ozone Exposures Upon Attaining Alternative

Level	Alternative standards		Pulmonary function decrements, FEV ₁ ≥15% associated with 8-hour exposures	Pulmonary function decrements, FEV ₁ ≥20% associated with 8-hour exposures	Moderate or severe pain on deep inspiration associated with 1-hour exposures
	Averaging time and form				
0.07	8-hour, 1 expected exceedance		3.0	0.4	0.3
0.08	8-hour, 1 expected exceedance		5.1	1.4	0.6
	8-hour, 5 expected exceedances		6.7	2.3	0.8
0.09	8-hour, 1 expected exceedance		7.7	2.7	0.9
	8-hour, 5 expected exceedances		9.5	3.8	1.3
0.12	1-hour, 1 expected exceedance		8.3	3.0	1.0

SMOG/OZONE The Science Calls for Action

CURRENT STANDARD	PROPOSED STANDARD
.12 ppm, 1-hour or .09 ppm, 8-hour	.08 ppm, 8-hour
20 million	33 million
4 million	7 million
5 million	8 million
74 million	122 million



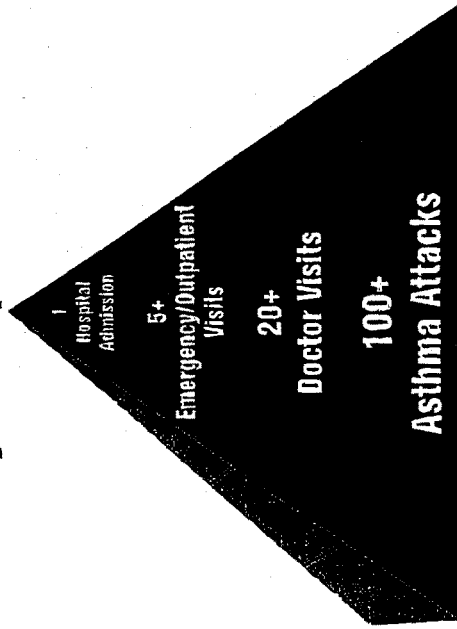
SOOT/PARTICULATE MATTER The Science Calls for Action

PM _{2.5} Study -Cities	Approximate Number of People Involved	Adverse Health Effect	Average Annual PM _{2.5} Concentration (µg/m ³)
Schwartz et al. (1996) -Boston, MA	2,300,000	Short-term Exposures: Premature Mortality	15.7
St. Louis, MO	2,400,000	Short-term Exposures: Premature Mortality	18.7
-Knoxville, TN	640,000	Short-term Exposures: Premature Mortality	20.8
Thurston et al. (1994) -Toronto, Canada	2,400,000	Short-term Exposures: Hospital Admissions	18.6
Schwartz et al. (1994) -Six Cities study	1,844 Children	Short-term Exposures: Respiratory Symptoms	18.0
Pope et al. (1995) -50 U.S. Cities	800,000	Long-term Exposures: Premature Mortality	18.0
Dockery et al. (1993) -6 U.S. Cities	5,500,000	Long-term Exposures: Premature Mortality	18.0



Hospital Admissions are the Tip of the Iceberg

For Every 1 Hospital Admission:



Cite: U.S. Department of Health and Human Services (1994) National Hospital Ambulatory Medical Care Survey: 1992 Summary. The New York Electricity Externality Study (1995) Rowe et al.



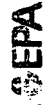
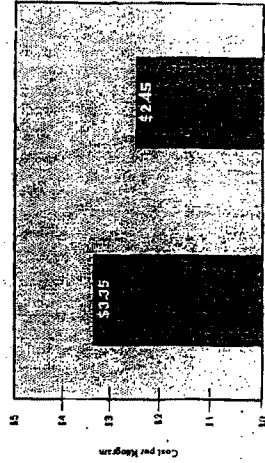
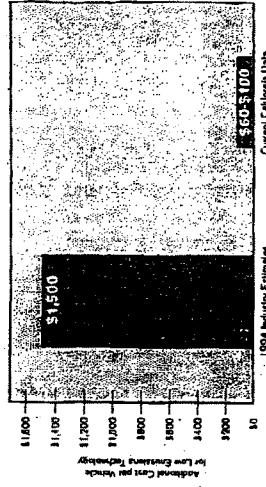
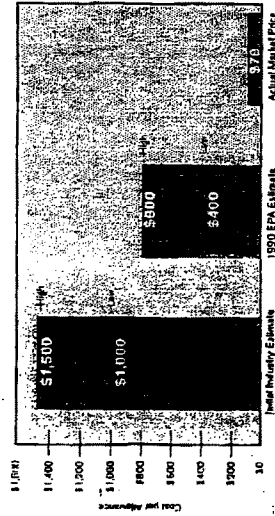
SOOT/PARTICULATE MATTER The Science Calls for Action

- "It was the consensus of the Panel that although our understanding of the effects of PM is far from complete, the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards."
- "There was also a consensus that a new PM_{2.5} NAAQS be established, with nineteen [of 21] Panel members endorsing the concept of a 24-hour and/or an annual PM_{2.5} NAAQS."
- Individual Panel members endorsed levels within the ranges of:
 - PM_{2.5} - 15-30 µg/m³ Annual Average
 - 20 - ≥ 75 µg/m³ 24-Hour

Source: Clean Air Scientific Advisory Committee (CASAC) Closure on Staff Paper for Particulate Matter; June 13, 1996

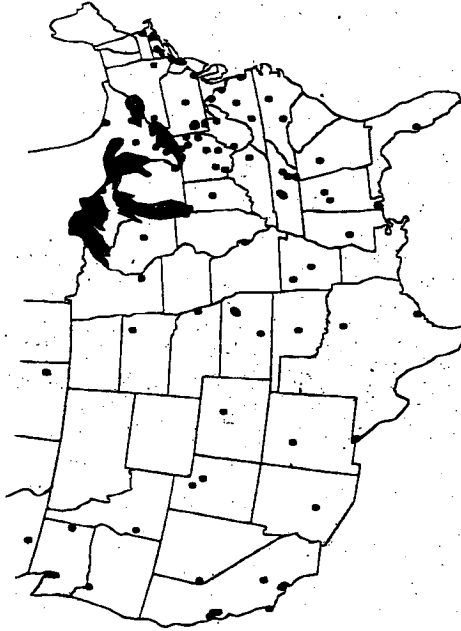


Costs: Historically Less Than Predicted



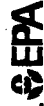
*Five year work plan
for the west*

Cities Studied for PM_{2.5} Data



- Alabama: Birmingham, Montgomery
- Alaska: Anchorage
- Arizona: Phoenix, Tucson
- Arkansas: Little Rock
- California: Anaheim, Bakersfield, Berkeley, Fresno, Los Angeles, Modesto, Oakland, San Diego, San Francisco, San Jose, Sacramento, Stockton
- Colorado: Denver
- Connecticut: Hartford
- Delaware: Dover
- Florida: Jacksonville, Miami, Orlando, Tampa
- Georgia: Atlanta
- Illinois: Chicago, Springfield
- Indiana: Indianapolis
- Iowa: Des Moines
- Kansas: Topeka
- Kentucky: Louisville
- Louisiana: New Orleans
- Maine: Portland
- Maryland: Baltimore
- Massachusetts: Boston
- Michigan: Detroit
- Minnesota: Minneapolis
- Mississippi: Jackson
- Missouri: St. Louis
- Montana: Billings
- Nebraska: Omaha
- Nevada: Las Vegas
- New Hampshire: Manchester
- New Jersey: Newark
- New Mexico: Albuquerque
- New York: Albany, Buffalo, New York City, Rochester
- North Carolina: Charlotte
- North Dakota: Bismarck
- Ohio: Columbus
- Oklahoma: Oklahoma City
- Oregon: Portland
- Pennsylvania: Philadelphia, Pittsburgh
- Rhode Island: Providence
- South Carolina: Columbia
- South Dakota: Pierre
- Tennessee: Nashville
- Texas: Austin, Dallas, Houston, San Antonio
- Utah: Salt Lake City
- Vermont: Montpelier
- Virginia: Richmond
- Washington: Seattle
- West Virginia: Charleston
- Wisconsin: Milwaukee
- Wyoming: Cheyenne

- Area: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming
- State: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming
- City: Anchorage, Anchorage, Anaheim, Anaheim, Bakersfield, Bakersfield, Berkeley, Berkeley, Fresno, Fresno, Los Angeles, Los Angeles, Modesto, Modesto, Oakland, Oakland, San Diego, San Diego, San Francisco, San Francisco, San Jose, San Jose, Sacramento, Sacramento, Stockton, Stockton
- City: Denver
- City: Hartford
- City: Dover
- City: Jacksonville, Jacksonville, Miami, Miami, Orlando, Orlando, Tampa, Tampa
- City: Atlanta
- City: Chicago, Chicago, Springfield, Springfield
- City: Indianapolis
- City: Des Moines
- City: Topeka
- City: Louisville
- City: New Orleans
- City: Portland
- City: Baltimore
- City: Boston
- City: Detroit
- City: Minneapolis
- City: Jackson
- City: St. Louis
- City: Billings
- City: Omaha
- City: Las Vegas
- City: Manchester
- City: Newark
- City: Albuquerque
- City: Bismarck
- City: Columbus
- City: Oklahoma City
- City: Salt Lake City
- City: Montpelier
- City: Richmond
- City: Seattle
- City: Charleston
- City: Milwaukee
- City: Cheyenne



RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR THOMAS

Question 1. After reading your testimony, you seem very confident that the science supports taking action on particulate matter. You mentioned several times about how important it is to have the best science available to us and to use that science in determining new standards. If you are so confident about this, I am curious as to why the EPA's own budget request for Fiscal Year 1998 points out the need for more money—and I quote—to research “the great uncertainty about PM and health effects”?

- That sounds to me like the EPA is admitting they don't know enough at this point about which particulates cause health effects. Why are you seeking \$26 million for health effects research if you are certain the current science says you should regulate PM_{2.5}?

Answer. Taking action to protect public health in light of the most recent scientific information available is not inconsistent with earmarking substantial resources to improve our scientific understanding for future reviews. Indeed, this responsible public health policy and research approach flows directly from the requirements of the Clean Air Act. The Act directs EPA to establish national ambient air quality standards (NAAQS) that protect public health with an adequate margin of safety, based on the most recent scientific criteria. These criteria address air pollution that “may reasonably be anticipated to endanger public health” [Clean Air Act, section 108(a)(1)(A)]. Yet, the Act also requires that the criteria and standards be reviewed every 5 years. If Congress intended that standards should only be established after all appropriate scientific research had been completed and all significant uncertainties resolved, there would be no need for these periodic reviews to update the science. In fact, it has long been the practice of the Clean Air Scientific Advisory Committee (CASAC) and the Agency to develop and review research needs at the conclusion of each criteria and standards review.

The courts have held that the margin of safety requirement for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, the Act requires the Administrator not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In the case of particulate matter (PM), the Administrator has responded to the health risks revealed in the most recent scientific assessment by proposing new standards for fine particles, while pursuing a vigorous research program to reduce the scientific uncertainties. She believes that this reflects a prudent and responsible public health policy that is soundly based on the available scientific information. This approach is exactly what was recommended by her independent scientific advisors. The strongest consensus from the CASAC was its near-unanimous support for maintaining PM₁₀ standards and establishing new standards for PM_{2.5}, and for continuing a comprehensive research program to improve our scientific understanding of the key issues.

If new standards are set, it would take several years to put a program in place to implement them with a series of measures over time. The effort to conduct monitoring and develop control programs will undoubtedly reveal additional scientific and technical information needs. The research done over the next few years could be of significant benefit in improving new control programs, and contribute much to the next criteria and standards review. A delay in establishing these standards would add several years to the time when significant health benefits can be realized, potentially resulting in tens of thousands of additional premature deaths and even larger numbers of individuals with air pollution-related illness and symptoms.

Whether the standards are set for PM₁₀ only or also include PM_{2.5}, there are unavoidable uncertainties at present with respect to the relative risk presented by various components of particulate matter. The Administrator places greater weight on the need to adequately control air pollution that is responsible for adverse effects than on the possibility we might also be controlling some component that may not be related to such effects. EPA believes that moving forward simultaneously on both health protection and research is the most appropriate approach, one that is consistent with both the philosophy and practice of establishing and reviewing ambient standards under the Clean Air Act.

Question 2. I noted with interest that the Administration and you responded to the concerns of the nation's Governors by asking the court for a 60-day extension

of the public comment period and issuance of the final rule for particulate matter. You stated: “it is critical for the American people to have a thorough, fair and informed public debate on the EPA proposal. To this end I recognize additional time is needed to responsibly assess and comment on our proposal.” As you know, on Monday the court granted EPA a 3-week extension of the two standards.

- What is the significance of three additional weeks?
- Given the Governors have to implement the ozone and particulate rules and have asked for a longer extension of the comment period—and given that you are only constrained by the court with regard to the particulate rule—if the nation’s Governors asked for a longer extension of the public comment period for the ozone rule would you grant such an extension?

• Are you letting the court drive the ozone timetable in a de facto manner?

Answer. The significance of the three additional weeks is that they represent the Court’s view of how much additional time was appropriate for public comment on the PM proposal, and of course, that they do allow additional time for interested parties to prepare comments. For the reasons discussed in the proposal notices, EPA stated its intent to review and, as appropriate, modify both standards on a similar schedule. Work on review of the ozone standard has been ongoing since 1992, predating the March 9, 1993 *Federal Register* notice that formally concluded the last review of the ozone standards. In that notice, which announced a decision not to revise the standards at that time, the Administrator announced her commitment to expedite the next review in light of new scientific evidence on the effects of ozone on human health that had not as yet been thoroughly peer reviewed. A number of public peer review meetings were held on the new studies and on draft chapters of the Criteria Document throughout 1993. In a February 1994 *Federal Register* notice, the Administrator announced a schedule for completion of the scientific assessment and review of the standards, including opportunities for public comment—this schedule called for proposal by the summer of 1996 and a final decision as to whether to revise the ozone standards by the summer of 1997.

Since that time there have been five public meetings of the CASAC to review both the Criteria Document and EPA’s Staff Paper. The EPA staff has also regularly briefed staff of the National Governors Association (NGA) and the States both prior to proposal and after proposal on what the science was showing. In addition, after proposal EPA briefed NGA and State staff on the proposed standards and the rationale for them. Numerous public meetings have also been held both prior to and after proposal to further inform the public on the science and EPA’s proposals.

The Administrator believes there has been ample time for all parties to understand the science and to develop comments on the EPA’s proposals. The Administrator is not letting the Court drive the ozone schedule. In fact, she chose to delay the proposal of the ozone standard and to place it on the same schedule as the particulate matter standard because of the benefits for developing integrated implementation strategies. The rationale for this decision was presented in an Advanced Notice of Proposed Rulemaking, published in the *Federal Register* on June 12, 1996. That delay in effect provided an additional 5 months for interested parties to review EPA’s assessments of the scientific and technical information bearing on whether the ozone standard should be revised, as well as staff and CASAC advice and recommendations on that issue, in preparation for the development of comments on the ozone proposal itself. The attached timeline highlights the pre-proposal activities discussed above.

As discussed in the proposal notice, important common factors between the two pollutants have been identified that have a significant bearing on the implementation of the ozone and particulate matter standards. Similar sources emit both pollutants (or their precursors) and both are formed under similar atmospheric conditions by precursor gases (e.g., nitrogen oxides, volatile organic compounds). These similarities provide opportunities for optimizing integrated strategies for reducing emissions that contribute to both ozone and fine particle pollution in the most cost-effective, efficient and flexible manner possible. As you note, the States and Governors have a significant role to play in implementing these standards. It is for this reason that EPA has established a Federal advisory committee, the FACA Subcommittee on Integrated Implementation of the Ozone and PM NAAQS and the Regional Haze Program under the Clean Air Act Advisory Committee (CAAAC), to advise on the development of an implementation approach that is flexible and allows for joint planning, as appropriate, to address these pollutants as well as the regional haze problem. The EPA has repeatedly demonstrated its willingness to work with the Governors and States to develop common sense approaches to addressing air pollution problems. This is best exemplified by EPA’s substantial support to the 37 states currently working together in the Ozone Transport Assessment Group. As we

go forward in developing our implementation policies, there will be significant opportunities for the Governors and States to participate and provide input.

Question 3. In the West we often have severe forest fires and brush fires during the dry summer months. The amount of particulate matter being emitted into the atmosphere by these fires is significant. Is it not possible that events like the Yellowstone fires of 1988 could put many cities out of attainment for particulate matter?

- How would the EPA separate out health effects from forest fires as compared to other contaminants?
- Has the EPA taken into account the unique geological, climatic and ecological differences in the Western States?

Answer. EPA has initiated several actions to address issues related to implementing the proposed standards in Western States. An ad hoc group has been formed under the FACA Subcommittee on Integrated Implementation to discuss issues peculiar to Western States. Also, a separate work group has been established under the Subcommittee to recommend approaches to issues directly related to planning for and minimizing the adverse health effects of wildland fires (both prescribed and unplanned wildfires). The work group includes representatives from Federal and State agencies that manage land and conduct prescribed burns.

In the past, forest fires have caused the current PM₁₀ air quality standards to be exceeded, but they have not caused an area to be designated nonattainment. The current 24-hour PM₁₀ standard must be exceeded more than once per year on average in an area to cause nonattainment. Furthermore, EPA recently issued a policy statement applicable to areas affected by natural events such as wildfires. A copy of the policy is attached. The policy allows states to discount PM₁₀ air quality data that results from natural events in certain circumstances provided that a plan is implemented to increase public awareness and minimize the health impacts of such events.

Episodic events such as forest fires would have even less influence on attainment of the proposed 24-hour PM standards. The EPA proposed to specify the form of the 24-hour standards to allow exceedances on 2 percent of monitored days. That proposal would allow the standards to be exceeded on average about 7 days per year with every-day monitoring.

Mass concentration measurements of particulate matter from many sources have been related to serious health effects in scientific studies; as a result, EPA's proposed standards rely on measurements using the Federal Reference Method to collect particles of certain sizes (e.g., PM_{2.5} and PM₁₀) that come from a wide variety of sources. Thus, the health effects from exposures to particulate matter from various sources would not be differentiated. However, in determining how best to implement these standards, States and local governments would have flexibility in deciding how to control various sources in the most cost-effective manner.

Question 4. We hear a lot of talk about protecting children and people at risk, such as the elderly. I completely understand the need to protect these groups and find it hard to believe that any of us would want to harm children or people who have a hard time breathing. That's simply ludicrous. We also hear a great deal of discussion about risk assessment and prioritizing risks. Isn't it true that most people—young and old—spend more time indoors being exposed to indoor air pollution?

- In EPA's own publication *The Inside Story: A Guide to Indoor Air Quality* (April 1995) it states: "A growing body of scientific evidence suggests that the air within homes and other buildings can be more seriously polluted than outdoor air, even in the largest most industrialized cities. Thus, for many people, the risks to health may be greater to exposure to air pollution indoors than outdoors."

- In EPA's recent report on air quality, it's documented that over the past 25 years, major air pollutants have decreased nationally by almost 30 percent. Wouldn't you agree that if we are truly concerned about priorities and sound public policy, we should be addressing indoor air pollution, since outdoor air pollution has declined and will continue to do so?

Answer. It is true that most people spend more time indoors than outdoors; this was a key consideration in evaluating the risk posed by particulate matter and ozone. EPA agrees that it is sound public policy to address all major environmental threats to public health. We also agree that indoor air pollution is of significant concern and, as noted below, EPA has been taking responsible steps to address this concern. However, we also believe it is important to fulfill the Clean Air Act mandate to revise the ambient air quality standards, as appropriate, to protect public health with a margin of safety, the issue that is at hand in this review.

EPA is proud that, through the cooperative effort of States, industry, the Federal Government, and the public, the country has made great strides to improve outdoor

ambient air quality. However, based on the record at the time of proposal, EPA's review of the most recent scientific information indicates that the current standards are not protective enough for ozone and PM. The Clean Air Act requires EPA to review the standards and any new scientific information for exactly this purpose—to determine if our national air quality standards are the correct ones. The most recent scientific information provides consistent and coherent evidence that serious health effects are occurring in children, the elderly, and other sensitive populations at PM and ozone concentrations at and below our existing standards.

All of the programs being implemented today to meet the existing ozone and PM standards will help meet both the current standards *and* any new or revised standards. By building implementation strategies for new standards around key existing control programs, we are working to build on the momentum of the nation's ongoing control efforts in order to provide public health protection as effectively and efficiently as possible—revising these standards will do nothing to slow this progress.

For 26 years, the Clean Air Act has promised American adults and children that they will be protected from the harmful effects of dirty air—based on the best available science. The Act requires that national air quality standards “are requisite to protect the public health,” including sensitive populations such as children at risk from the harmful effects of pollution. EPA's proposed ozone standard would increase protection for an estimated 122 million Americans from harmful ozone exposures, including 33 million children, 7 million asthmatics, and 8 million people with other respiratory diseases.

As part of this review of the ozone standard, EPA conducted a state-of-the-art exposure assessment looking at the at-risk population exposures to tropospheric ozone, including children and people who work for their living out of doors. Children tend to spend more time outdoors than adults. Because children engaged in outdoor playing have increased respiration rates, they may experience higher exposures to ozone and other air pollution. Although residing in air conditioned buildings may provide some protection from indoor ozone exposures, not everyone can afford air conditioning and many people and children are outside (or have the windows open) on summer days when ozone levels may be high.

With regard to particulate matter, outdoor air pollution can be a major source of indoor pollution. In a non-smoking household, for instance, particles from outdoor sources contribute on average as much as 76 percent of the PM_{2.5} measured indoors (Source: Ozkaynak et al., 1993a, Criteria Document p. 7–38). Among the population's most sensitive to the effects of particulate matter are the elderly, who typically spend more time indoors than the norm. This is one of the reasons it is critical to revise the standards to focus on fine particles, which not only readily penetrate to the indoor environment but remain suspended in the indoor air for substantially longer periods than do larger particles.

With respect to promoting good indoor air quality, it is important to remember that outdoor air establishes the base pollutant concentration indoors; indoor sources add to that base to create indoor conditions. One of the keys to good indoor air quality is clean outdoor ambient air, since the technique most frequently used to control indoor air quality is ventilation with outdoor air.

EPA is currently addressing indoor air pollution through voluntary measures, including the development and dissemination of guidance to the owners and operators of commercial buildings and schools, to consumers, home owners and building occupants, and to other influential audiences such as public and environmental health advocates, and building design and construction professionals, about the most effective ways to prevent indoor air problems from occurring, and resolve them if they do. Working with over 650 affiliates of national organizations such as the American Lung Association, the Consumer Federation of America, and the National Association of Counties, EPA will be raising awareness about indoor air quality problems and encouraging actions to prevent or resolve them in communities across the nation. More than 20,000 copies of guidance material EPA published in 1995 for schools wishing to prevent or solve indoor air quality problems (“Indoor Air Quality Tools for Schools”) will have been distributed to American schools, and some 1,500 schools are expected to implement our recommendations this year. The “Building Air Quality Guide” for commercial building owners and managers that EPA published in 1991 has become the standard of care for proper building maintenance. A multi-year study to characterize the condition of the indoor environment in a representative sample of office buildings across the country is well underway; 70 building profiles and occupant perception questionnaires, out of 100 buildings planned for inclusion in the study, will have been completed by the end of this fiscal year. Our public outreach and education efforts continue to be a cornerstone of our indoor air quality program, with clearinghouses and hotlines responding to some 60,000 in-

quiries per year and distributing more than 1 million information documents annually.

In short, we believe we are taking appropriate steps to ensure Americans enjoy clean, healthy air both in the outdoor environment and indoors.

Question 5. What costs will state and local communities have to incur to comply with the new standards? What will the costs be to implement the new monitoring plans that states will be required to have in place?

Answer. Sample estimates of the potential control costs to local government agencies associated with the proposed new particulate matter standard were provided in the November 1996 particulate matter regulatory impact analysis (RIA). These estimates are based on assumptions regarding how State and local government agencies will implement control measures to achieve any new standards. Potentially significant costs to county governments were estimated for 10 percent of the small sample of county governments that were assessed. The estimated control costs to State and local government agencies associated with the proposed new ozone standard were not estimated in the November 1996 ozone RIA, but are expected to be insignificant since few ozone precursor control measures that were identified in the RIA are directly controlled or owned by State and local governments.

Administrative costs were not estimated in the November 1996 ozone and particulate matter RIAs but are expected to be very small relative to total control costs. The revised ozone/particulate matter RIA to be completed in July 1997 will include estimates of administrative costs.

The EPA's proposed monitoring regulations for PM_{2.5} require a new PM_{2.5} monitoring network which is currently estimated to cost a total of \$70.8 million for 1200 stations. Our current projection is that States and EPA will share the cost of phasing this network in over the next 4 years. Because we are proposing to maintain PM₁₀ standards, with modest revisions, we project gradual offsets from the current PM₁₀ monitoring program. We are currently developing interim PM program guidance which continues much of the PM₁₀ program while transitioning to the PM_{2.5} program. Of the estimated \$70.8 million cost for the PM_{2.5} network, \$4.2 million has been acquired from offsets from the current PM₁₀ monitoring program. The remainder, \$66.6 million, will be needed in new funding from fiscal year 98 through the year 2000 to support this new NAAQS monitoring network. Essentially, all of these new costs will be incurred during 1998 to 2000. EPA will provide 60 percent of this burden through the Federal 105 Grant funds and assumes that the other 40 percent of this burden would be provided by State and local agencies.

The initial samplers would be allocated to provide geographic coverage with added initial emphasis on high population, high potential PM_{2.5} pollution areas and high ozone areas. All new samplers will include both Federal Reference Method monitors, special purpose monitors, and continuous PM analyzers. In addition, special monitoring studies are needed with an emphasis on designing adequate networks to lay the ground work for future strategy development.

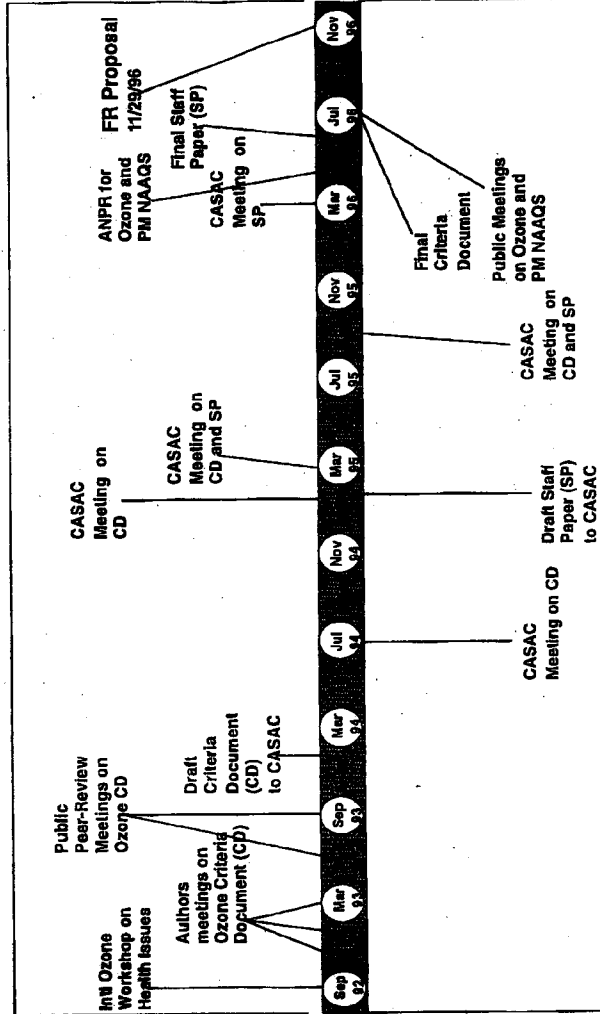
The table below outlines the current strategy for phasing in the PM_{2.5} monitors and phasing-out of some of the PM₁₀ monitors. The table identifies the number of PM₁₀ and PM_{2.5} sites and the estimated total cost of the PM₁₀ and PM_{2.5} monitoring networks.

	Approximate No. of Operational Sites			Estimated National PM Cost [In millions of dollars]		
	Year	PM ₁₀	PM _{2.5} *	PM ₁₀	PM _{2.5}	Total
0	1997	1600	200	15.9	4.2	20.1
1	1998	1400	600	12.6	18.6	29.9
2	1999	1000	1000	9.8	24.0	33.8
3	2000	600	1200	6.7	24.0	30.7

* Totals include approximate number of sites operating at the end of the year.

[Attachments to Questions 2 and 3 from Senator Thomas follow:]

History of Ozone NAAQS Review





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 30 1996

OFFICE OF
AIR AND RADIATIONMEMORANDUM

SUBJECT: Areas Affected by PM-10 Natural Events

FROM: Mary D. Nichols *Mary D. Nichols*
Assistant Administrator
for Air and Radiation (6101)

TO: Director, Air, Pesticides and Toxics Management
Division, Regions I and IV
Director, Air and Waste Management Division,
Region II
Director, Air, Radiation and Toxics Division,
Region III
Director, Air and Radiation Division,
Region V
Director, Air, Pesticides and Toxics Division,
Region VI
Director, Air and Toxics Division

Purpose

This memorandum sets forth the Environmental Protection Agency's (EPA's) policy for protecting public health in areas where the PM-10 (particulate matter having a nominal aerodynamic diameter less than or equal to 10 microns) national ambient air quality standards (NAAQS) are violated due to natural events. This policy will be followed in implementing the PM-10 NAAQS until it is superseded.¹ The need for revisions to this policy will be considered by EPA, State agencies and the Federal Advisory Committee Act's Particulate Matter/Ozone/Regional Haze Subcommittee if the NAAQS for particulate matter are revised.

Three categories of natural events have been identified as affecting the PM-10 NAAQS: (1) volcanic and seismic activity, (2) wildland fires, and (3) high wind events. These PM-10

¹This document contains EPA policy and, therefore, does not establish or affect legal rights or obligations. It does not establish a binding norm and it is not finally determinative of the issues addressed. In applying this policy in any particular case, the EPA will consider its applicability to the specific facts of that case, the underlying validity of the interpretations set forth in this memorandum, and any other relevant considerations, including any that may be required under applicable law and regulations.

MEMORANDUM

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for Air and Radiation (6101)

TO: Director, Air, Pesticides and Toxics Management
Division, Regions I and IV
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interpretations set forth in this memorandum, and any other relevant considerations, including any that may be required under applicable law and regulations.

natural events are defined further below. If other significant categories of natural events are identified, they may be added to this policy in the future.²

Background

Prior to the 1990 Clean Air Act Amendments (Act), the Guideline on the Identification and Use of Air Quality Data Affected by Exceptional Events (exceptional events guideline) and Appendix K to 40 CFR, part 50, were issued by EPA to address, in part, the situation where natural sources strongly influence an area's PM-10 air quality. To avoid imposing potentially unreasonable State implementation plan (SIP) requirements on such areas, EPA provided for the exclusion of certain natural source data from nonattainment determinations. Thus, Appendix K provides, in part, that measured exceedances of the PM-10 NAAQS in an area may be discounted from decisions regarding nonattainment status if the data are shown to be influenced by uncontrollable events caused by natural sources of particulate matter. The 1986 exceptional events guideline contains EPA's guidance regarding the process States should follow when dealing with PM-10 air quality data that may be eligible for the adjustments authorized under section 2.4 of Appendix K.

Subsequently, the Act added section 188(f) which provides EPA with discretionary statutory authority to waive either a specific attainment date or certain planning requirements for serious PM-10 nonattainment areas that are impacted significantly

by nonanthropogenic sources. The EPA states in current PM-10 guidance documents that it interprets the section 188(f) waiver provision to mean that the data exclusion policy contained in Appendix K and the procedures described in the exceptional events guideline no longer apply.

²Other types of temporary or exceptional events that can impact ambient PM-10 concentrations are structural fires, chemical spills, industrial accidents, and clean-up activities following a major disaster. The EPA's Guideline on the Identification and Use of Air Quality Data Affected by Exceptional Events, July 1986, is still applicable for treating air quality data resulting from these types of exceptional, anthropogenic events.

Under this natural events policy, those statements no longer reflect EPA's interpretation of the relationship between the section 188(f) waiver provision, Appendix K, and the exceptional events guideline and should be treated as revised to the extent described herein.

In establishing this natural events policy, EPA now believes that, under certain circumstances, it is appropriate to again exclude PM-10 air quality data that are attributable to uncontrollable natural events from the decisions regarding an area's nonattainment status. The discussion in the Appendix at the end of this memorandum briefly describes the legal rationale underlying this revised interpretation.

Description of Policy

The policy described in this document addresses PM-10 NAAQS violations caused by natural events in areas designated unclassifiable or attainment. It also addresses certain reclassification and redesignation questions for PM-10 nonattainment areas. This policy applies at the time the State determines that a PM-10 NAAQS has been violated due to natural events and addresses the question of what should be done to protect public health. The policy provides that EPA will: (1) exercise its discretion under section 107(d)(3) not to redesignate areas as nonattainment if the State develops and implements a plan to respond to the health impacts of natural events; and, (2) redesignate nonattainment areas as attainment by applying Appendix K, on a case-by-case basis, to discount data in circumstances where an area would attain but for exceedances that result from uncontrollable natural events.

The guiding principles followed in developing this policy are:

1. Protection of public health is the highest priority of Federal, State, and local air pollution control agencies.
2. The public must be informed whenever the air quality in an area is unhealthy.³

³The air quality is considered unhealthy whenever the 24-hour PM-10 NAAQS is exceeded. The short-term PM-10 NAAQS is exceeded

3. All valid ambient air quality data should be submitted to the EPA Aerometric Information Retrieval System (AIRS) and made available for public access.

4. State and local agencies must take appropriate reasonable measures to safeguard public health regardless of the source of PM-10 emissions.

5. Emission controls should be applied to sources that contribute to exceedances of the PM-10 NAAQS when those controls will result in fewer violations of the standards.

when the 24-hour average PM-10 concentration is greater than 150 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$). The 24-hour NAAQS is violated when the expected number of days per calendar year with a 24-hour average concentration above $150 \mu\text{g}/\text{m}^3$ is greater than 1.0, as determined by procedures described in Appendix K.

Definition of PM-10 Natural Events

Volcanic and seismic activities: Ambient PM-10 concentrations caused by volcanic eruptions or seismic activity will be treated as due to natural events. Volcanic eruptions contribute to ambient PM-10 concentrations in two ways: (1) with emissions of primary PM-10 (e.g., ash), and (2) with emissions of precursor pollutants (e.g., sulfur dioxide) that react to form secondary particulate matter. Seismic activity (e.g., earthquakes) can also contribute to ambient PM-10 concentrations by shaking the ground, causing structures to collapse and otherwise raising dust (primary PM-10 emissions).

Also, emissions caused by anthropogenic activities that re-entrain volcanic ash during the first year (12 months) following an event will be treated as due to the natural event. One year is considered adequate time for cleaning ash deposits from areas where anthropogenic activities (e.g., vehicle traffic) would cause reentrainment. After 1 year, only emissions resulting from reentrainment of ash by high winds will be treated as due to a natural event.

Wildland fires: Ambient PM-10 concentrations caused by smoke from wildland fires will be treated as due to natural events if the fires are unwanted fires, not designated or managed as prescribed fires, and requiring appropriate suppression action by the wildlands manager.⁴

For the purposes of this policy, wildland fire natural events are limited to unwanted fires that do not meet a prescription (wildfires) and, therefore, require appropriate suppression actions. Wildland prescribed fires, burning of

⁴The EPA recognizes and endorses the Federal Wildland Fire Policies adopted by the Departments of Interior and Agriculture in December 1995. These policies refer to all fires on sparsely populated lands managed by Federal agencies (e.g., national parks, national forests, grasslands, etc.) as wildland fires. The wildland fires term includes unwanted fires that do not meet a prescription (wildfires), management-ignited prescribed fires, and naturally-ignited fires that meet a prescription (prescribed natural fire). Only wildland fires that meet a prescription may be used to accomplish land and resource management objectives.

forest harvest residues, agricultural burning, and fires for land clearing are not covered by this natural events policy. The EPA will develop broader guidance in the near future to address issues raised by smoke emissions from wildland prescribed fires and other policy issues surrounding prevention of significant deterioration, conformity, visibility protection programs and regional haze.

High Winds: Ambient PM-10 concentrations due to dust raised by unusually high winds will be treated as due to uncontrollable natural events under the following conditions: (1) the dust originated from nonanthropogenic sources, or (2) the dust originated from anthropogenic sources controlled with best available control measures (BACM).⁵

The BACM must be implemented at contributing anthropogenic sources of dust in order for PM-10 NAAQS exceedances to be treated as due to uncontrollable natural events under this policy. Therefore, BACM must be implemented for anthropogenic dust sources contributing to NAAQS exceedances in attainment and unclassifiable areas and in moderate PM-10 nonattainment areas. In unclassifiable and attainment areas, BACM must be implemented for those contributing sources for which it has been defined within 3 years after the first NAAQS violation attributed to high wind events or from the date of this policy. In these same areas, implementation should be as expeditious as practicable for sources for which BACM are undefined.

The conditions that create high wind events vary from area to area with soil type, precipitation and the speed of wind gusts. Therefore, the State must determine the unusually high wind conditions that will overcome BACM in each region or subregion of the State.

Response to NAAQS Violations

If natural events cause ambient concentrations of PM-10 to violate a NAAQS, a plan should be developed to address future

⁵BACM for PM-10 are techniques that achieve the maximum degree of emissions reduction from a source as determined on a case-by-case basis considering technological and economic feasibility (59 FR 42010, August 16, 1994).

events.⁶ A natural events action plan (NEAP) should include commitments to:

1. Establish public notification and education programs. Such programs may be designed to educate the public about the short-term and long-term harmful effects that high concentrations of PM-10 could have on their health and inform them that: (a) certain types of natural events affect the air quality of the area periodically, (b) a natural event is imminent, and (c) specific actions are being taken to minimize the health impacts of events.

2. Minimize public exposure to high concentrations of PM-10 due to future natural events. Programs to minimize public exposure should: (a) identify the people most at risk, (b) notify the at-risk population that a natural event is imminent or currently taking place, (c) suggest actions to be taken by the public to minimize their exposure to high concentrations of PM-10, and (d) suggest precautions to take if exposure cannot be avoided.

3. Abate or minimize appropriate contributing controllable sources of PM-10. Programs to minimize PM-10 emissions may include:

(a) volcanic and seismic activities - cleaning ash and dust deposits from areas where it would be re-entrained into the air by anthropogenic activities;

(b) wildland fires - prohibition of other burning activities during wildland fire events and steps to minimize fuel loadings in areas vulnerable to fire. Appropriate suppression actions, as determined by the wildlands manager, should be taken for fires that do not meet a prescription. The Federal Wildland Fire Policies require that fire management plans (FMP) be developed

⁶The annual PM-10 NAAQS is violated if the expected average annual arithmetic mean concentration for the past 3 calendar years is greater than 50 $\mu\text{g}/\text{m}^3$. Several elevated 24-hour PM-10 concentrations caused by natural events can potentially cause the annual NAAQS (which is an annual arithmetic mean of 24-hour concentrations) to be exceeded. If natural events cause the annual NAAQS to be violated, one NEAP for the area will cover both the 24-hour and annual NAAQS.

for all Federal lands with burnable vegetation.⁷ It is anticipated that a goal of FMP will be to prevent NAAQS exceedances caused by wildland fires. Therefore, EPA envisions treating future FMP as acceptable plans for mitigating the public health impacts of smoke from wildland fires on Federal lands. Similar FMP should be developed to serve the same purpose for State and private wildlands.

(c) High winds - application of BACM to any sources of soil that have been disturbed by anthropogenic activities. The BACM application criteria require analysis of the technological and economic feasibility of individual control measures on a case-by-case basis. The NEAP should include analyses of BACM for contributing sources. The BACM for windblown dust include, but are not limited to, application of chemical dust suppressants to unpaved roads, parking lots and open areas; dust suppression at construction sites; use of conservation farming practices on agricultural lands; tree rows and other physical wind breaks;

⁷FMP are not in place for all Federal lands at this time. These plans will be developed by Federal land managers in conjunction with all stakeholders including Federal, State and local air management agencies. The FMP will integrate fire, as a natural ecological process, into land and resource management plans and will form the basis for management actions taken on wildland fires. The FMP must include prescriptions for any use of fire to meet land and resource management objectives.

The EPA anticipates that FMP will achieve an acceptable balance between forest health and public health concerns. Public health concerns caused by the potential effects of smoke on air quality from wildland fires will be addressed in FMP through smoke management plans and other measures. Smoke management plans attempt to minimize smoke impacts by monitoring fire behavior, meteorology and air quality during the fire and by publicly announcing forecasts of likely smoke conditions in communities impacted by ongoing fires. Since FMP will treat fire as a natural ecological process, the impact of wildland fires on air quality and regional haze is expected to increase in the future. Therefore, EPA will encourage Federal land management agencies to support air quality monitoring near fires, to assess air and haze impacts, and to develop a fire information data base and regional-scale smoke management plans.

restricting or prohibiting recreational off-road vehicle activities; and use of surface coverings. If BACM are not defined for the anthropogenic sources in question, step 4 below is required.

4. Identify, study and implement practical mitigating measures as necessary. The NEAP may include commitments to conduct pilot tests of new emission reduction techniques. For example, it may be desirable to test the feasibility and effectiveness of new strategies for minimizing sources of windblown dust through pilot programs. The plan must include a timely schedule for conducting such studies and implementing measures that are technologically and economically feasible.

5. Periodically reevaluate: (a) the conditions causing violations of a PM-10 NAAQS in the area, (b) the status of implementation of the NEAP, and (c) the adequacy of the actions being implemented. The State should reevaluate the NEAP for an area every 5 years at a minimum and make appropriate changes to the plan.

Form and Timing of the Response

The NEAP should be developed by the State air pollution control agency in conjunction with the stakeholders affected by the plan. Development of a NEAP for wildland fires should include input from Federal, State and private land managers in areas vulnerable to fire. Also, agencies responsible for suppressing fires and the citizens in the affected area should be involved in developing the plan. Development of a NEAP for high-wind events should include input from Federal, State and private managers of open desert lands, rangelands, agricultural lands; the construction industry; and organizations promoting the use of recreational off-road vehicles. Development of a NEAP for volcanic and seismic activities should include input from geophysicists and public works officials who will be responsible for ash removal and disposal. The plan should include documented agreements among the stakeholders as to planned actions, the implementation schedule, and the parties responsible for carrying out those actions.

At a minimum, States should develop NEAP for any areas where natural events cause or have caused a PM-10 NAAQS to be violated within 18 months of the violation or the date this policy is

issued. The NEAP should be made available for public review and comment and may, but are not required to, be adopted as revisions to the SIP if current SIP rules are not revised. Final plans should be submitted to EPA for review and comment.

Documentation of Natural Events

In circumstances where a State has reason to believe that natural events have caused measured exceedances of the NAAQS, the State is responsible for establishing a clear causal relationship between the measured exceedance and the natural event. Supporting documentation concerning the natural event could include filter analysis, meteorological data (e.g., wind speed and wind direction to support a source receptor relationship), modeling and receptor analysis, videos and/or photographs of the event and the resulting emissions, maps of the area showing sources of emissions and the area affected by the event, and news accounts of the event.

In the case of high-wind events where the sources of dust are anthropogenic, the State must document that BACM were required for those sources, and the sources were in compliance at the time of the high-wind event. If BACM are not required for some dust sources, the NEAP developed must include agreements with appropriate stakeholders to minimize future emissions from such sources using BACM.

The type and amount of documentation provided for each event should be sufficient to demonstrate that the natural event occurred, and that it impacted a particular monitoring site in such a way as to cause the PM-10 concentrations measured. This documentation should also provide evidence that, absent the emissions from the natural event, concentrations of PM-10 at the monitoring site under consideration would not cause a NAAQS exceedance.

The State should also make the documentation of natural events and their impact on measured air quality available to the public for review. This may be accomplished through a number of means, such as the publishing of newspaper announcements, periodic reports on air quality in the area, and through public hearings. This would serve to allow the public an opportunity to comment on whether the causal relationship between the natural event and the air quality measurement is convincing. Also, open

hearings, where State and local regulatory boards review the documentation, are useful forums in which to notify the public of potentially-important policy decisions.

When air quality data affected by a natural event are submitted to EPA for inclusion into the AIRS data base, the State should request that a flag be placed on the data to indicate that a natural event was involved. Documentation to support the flagged data should be maintained by the State. A copy of the documentation should be sent to the relevant EPA Regional Office monitoring representative no later than 180 days from the time the exceedance occurred or from the date of this policy for past events. The Regional Office will acknowledge receipt of the documentation and confirm that the natural event data were flagged within 60 days.

Current PM-10 Nonattainment Areas

States may request that a moderate nonattainment area not be reclassified as serious if it can be demonstrated that the area would attain the standards by the statutory attainment date but for emissions caused by natural events. Similarly, States may request redesignation of nonattainment areas to attainment if it can be demonstrated that the area would be meeting the NAAQS but for the emissions caused by natural events. This policy applies to emissions caused by natural events that have occurred since January 1, 1994.⁸

Approval of the above requests will be made by EPA on a case-by-case basis as determined by the sufficiency of the information submitted by the State to substantiate its claim. At a minimum, the State must have adopted a SIP for the area which demonstrates that, but for the emissions from natural events, the area would be able to attain the NAAQS. All of the requirements under section 107(d)(3)(E) of the Act must also be satisfied before an area can be redesignated to attainment. Those

⁸The 1990 Amendments to the Clean Air Act required that control measures for anthropogenic sources in PM-10 nonattainment areas be implemented by the end of 1993. Therefore, this policy is made retroactive to January 1, 1994 so that NAAQS exceedances that may prevent areas from having sufficient clean air quality data to meet the standards will be covered by this policy.

requirements include the submittal of a maintenance plan under section 175A, among other things. The maintenance plan for areas affected by natural events must include a NEAP.

Failure to Submit a Natural Events Action Plan

If a State fails to submit an adequate NEAP within 18 months in response to violations of a PM-10 NAAQS, EPA will notify the governor of the State that the area should be redesignated as nonattainment. The EPA's action, in such instances, would be authorized under the Act based on the conclusion that the health of citizens affected by such events is not being protected by the State.

Once the area violating the NAAQS is designated nonattainment, the State will be required to adopt a federally-enforceable SIP revision and address the sources of PM-10 emissions. Most likely, the SIP revision will include many of the same mitigative measures that could have been included in a NEAP.

APPENDIX

INTERPRETATION OF THE CLEAN AIR ACT (ACT) AS AMENDED IN 1990

Section 107(d)(4)(B) of the Act, as amended in 1990, provided EPA with the authority to designate initial areas as nonattainment for PM-10. Where such determinations involved an assessment of a potential PM-10 nonattainment area's air quality data, Congress expressly required such assessments to be made in accordance with Appendix K (section 107(d)(4)(B)(ii)). Since, upon enactment, Congress did not alter or revise Appendix K in any way, all the provisions of Appendix K, including section 2.4, remained applicable under the Act. Among other things, section 2.4 authorizes EPA to discount air quality data that are attributable to "an uncontrollable event caused by natural sources" of PM-10. Consequently, if an area's nonattainment problem was attributable to uncontrollable natural sources, application of section 2.4 of Appendix K would allow the data from the uncontrollable natural event to be excluded from regulatory determinations regarding an area's nonattainment status.

The Act also added section 188(f) which specifically addresses the adverse influence of nonanthropogenic PM-10 sources. This section provides EPA with discretionary authority to waive a specific attainment date for all areas or certain planning requirements for serious PM-10 nonattainment areas that are significantly impacted by nonanthropogenic sources.

The EPA previously interpreted the inclusion of such an express waiver provision in the 1990 Amendments as implying that Congress may have intended to limit the application of section 2.4 of Appendix K. The argument in support of this interpretation was that in contrast to section 2.4 of Appendix K, which contemplates the discounting of data due to emissions from certain events, the section 188(f) waiver provisions envisioned that adjustments prompted by adverse air quality impacts that are attributable to data from natural uncontrollable sources of PM-10 should be made only after all the data have been considered and the area has been designated nonattainment.

The EPA, however, believes that this is not the only reasonable interpretation of the Act's provisions that is possible. The EPA believes that the congressional directive in section 107(d)(4)(B)(ii) to base designation decisions on Appendix K, and the differences in how section 188(f) and

Appendix K address issues related to emissions from natural sources, indicate that it is not necessary to conclude that section 188(f) limits the application of section 2.4 of Appendix K. Rather, it is possible to view both section 188(f) and section 2.4 of Appendix K as being operative and dealing with related but distinct aspects of the issues connected with emissions from natural PM-10 sources.

The starting point for this analysis is section 107(d)(4)(B)(ii), which, by operation of law, designated nonattainment any area with data showing a violation of the PM-10 NAAQS before January 1, 1989 "(as determined under part 50, appendix K of title 40 of the Code of Federal Regulations)." In that section, Congress required the use of Appendix K in designating areas nonattainment without indicating that any portion of Appendix K was to be considered invalid. Thus, that provision indicates that Congress intended designation decisions to be based on that appendix, including the procedures in section 2.4 regarding exceptional events.

Notably, section 2.4 defines an exceptional event as "an uncontrollable event caused by natural sources of particulate matter or an event that is not expected to recur at a given location." Thus, exceptional events include both uncontrollable natural sources and nonrecurring events related to any kind of source of particulate matter. Section 2.4 further provides that data from such events may be discounted (i.e., EPA may compensate for such data or exclude such data entirely from decisions regarding an area). Consequently, Appendix K contemplates that data from "exceptional events" may be discounted, including, but not limited to, data due to emissions from uncontrollable natural events.

On the other hand, section 188(f), which was enacted by Congress in the same amendments as section 107(d)(4)(B)(ii), discusses PM-10 natural sources in terms of whether they are "anthropogenic" or "nonanthropogenic." It does not discuss such sources or emissions in the terms of Appendix K (i.e., it does not discuss matters in terms of exceptional or nonexceptional events, nor does it distinguish between uncontrollable and controllable natural sources). In general, section 188(f) provides that EPA may waive certain requirements where EPA determines that anthropogenic sources do not contribute significantly to a violation of the PM-10 standard, and that EPA may waive a specific attainment date if it determines that the

contribution of nonanthropogenic emissions to a violation is demonstrated to be "significant."

As Congress, without express exception, directed the use of Appendix K in determining whether areas were attaining the PM-10 standard, EPA believes it is reasonable to interpret section 188(f) as not limiting the use of that appendix, provided that such an interpretation does not render section 188(f) invalid. The EPA believes that the approach taken in this natural events policy does not do that, and that it represents a reasonable harmonization of these provisions of the Act and the language of Appendix K regarding exceptional events.

Under EPA's revised interpretation, section 188(f) continues to have force and effect. As section 188(f) addresses the issues in terms of "anthropogenic" and "nonanthropogenic" sources, not in terms of exceptional events (which are defined in Appendix K as both uncontrollable natural events and nonrecurring events from both natural and other sources), it is possible to view the waivers of section 188(f) as being potentially applicable only to areas that are designated nonattainment because the data do not qualify for adjustment under Appendix K. For such areas, it may be reasonable and appropriate to grant waivers from some requirements that simply do not make sense in light of the nature of the sources generating the PM-10 problem in the area. Thus, EPA's new interpretation does not render section 188(f) meaningless. Consequently, EPA believes that the exercise of its discretionary authority under Appendix K to discount or de-weight air quality data that are affected by uncontrollable natural sources of PM-10 is reasonable and appropriate.

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR BAUCUS

Question 1. What level of tropospheric ozone does EPA consider to be due to background concentrations?

Answer. As defined (with CASAC concurrence) in this review, background ozone concentrations are those that would be observed in the U.S. in the absence of anthropogenic emissions of VOCs and NO_x in North America.

Background ozone concentrations will vary by geographic location, time of day, weather, altitude and season. Analyses of air quality values at remote sites are the basis for developing estimates of ozone concentrations attributable to background sources (see answer to Question 2 below). Such analyses produced an estimated range of daily 1-hour maximum ozone values near sea level of 0.03 to 0.05 ppm during the ozone season. Because the distribution of ozone air quality values at remote sites is relatively flat, a reasonable estimate of the 8-hour daily maximum ozone background during the summer season is also 0.03 to 0.05 ppm. These analyses also show that 1- and 8-hour ozone background concentrations will typically be much lower than 0.05 ppm. These estimates of background levels of ozone were carefully assessed during the development of the ozone Staff Paper and were explicitly agreed upon by CASAC.

Question 2. Are all background concentrations due to naturally occurring ozone precursors? If not, what level of background concentrations would be the result of naturally occurring ozone precursors? What else contributes to background concentrations?

Answer. As defined in this review, background concentrations include contributions both from natural sources and from "global" sources of anthropogenic emissions.

The natural component of background concentrations originates from three sources: the intrusion of ozone to ground level from the stratosphere, the photochemically initiated oxidation of biogenic and geogenic methane and carbon monoxide, and the photochemically initiated oxidation of biogenic VOCs. The magnitude of the natural component of background ozone concentrations cannot be precisely determined because of the role of long-range transport of anthropogenic precursors and/or ozone.

The "global" component includes the global transport of non-North American emissions of ozone precursors that are uncontrollable by emission control strategies in North America.

Question 3. Some areas in the US have experienced days when rural concentrations have been measured at levels at or above 70 ppb. How is it determined that ozone measurements are due to background concentrations? What rural areas in the country have experienced concentrations in excess of 50 ppb? Will any area in the U.S. be designated as nonattainment due purely to background levels under the proposed standards?

Answer. Remote areas, used to estimate background ozone concentrations, are generally removed from the influence of urban area emission sources. Rural areas, on the other hand, are areas that typically have no large local emission sources, but could well be affected by regional transport of controllable anthropogenic precursors and/or ozone from urban area sources. Ozone concentrations measured at rural sites usually consist of both locally produced or transported background ozone, and ozone or ozone precursors resulting from near or long-range transport from urban areas.

It is true that at rural sites 1-hour ozone concentrations can exceed 70 ppb (0.07 ppm). The Staff Paper makes it clear that the component consisting of background ozone is only a fraction of rural ozone concentrations, which are clearly increased by human activity throughout the U.S.

Based on assessments of air quality values at remote sites, background concentrations of ozone alone will not cause any area to fail to meet the standard. To the extent that rural areas experience transport of anthropogenic precursors and/or ozone, such concentrations would be reduced by national implementation strategies designed to address transport. The FACA Subcommittee on Integrated Implementation is examining the issue of rural transport areas and may make specific recommendations regarding how to handle program development for these areas. At this point in time, the general direction these discussions have taken is to recognize that areas which measure violations of the ozone NAAQS may or may not be responsible for the violations. With this in mind, the FACA Subcommittee is considering how to structure an implementation program that recognizes this reality.

Question 4. The EPA recently completed the Supplemental Ozone Exposure and Health Risk Analysis. Please explain the reason for this new analysis and the implications for the proposed ozone standard.

Answer. The EPA's proposal notice and Staff Paper cited ozone exposure and health risk estimates for "outdoor children" associated with just meeting the current 0.12 ppm, 1-expected exceedance standard and several alternative 1- and 5-expected exceedance, 8-hour standards. The methods used in the exposure and risk analyses and the selection of alternative standards to be analyzed were reviewed with the CASAC during the period from December 1993 through March 1994. Given the early selection of options to be analyzed, EPA indicated that additional alternatives might be analyzed later in the process. In conjunction with the decision to propose and take comment on various concentration-based forms of an 8-hour standard, EPA staff initiated efforts to develop supplemental exposure and risk estimates specifically for the proposed standard, alternative 8-hour standards, and the current 0.12 ppm, 1-hr standard.

Several technical revisions were made in preparing the supplemental analyses based on what was learned during the development and review of the original and supplemental analyses. The revised exposure and risk estimates and technical support documents describing the methods and results were placed in the public rule-making docket on February 12, 1997. The availability of the supplemental reports was announced in the *Federal Register* notice extending the public comment period. EPA is continuing its work on the supplemental analysis and evaluating public comments received on it.

While the absolute magnitude of the exposure and risk estimates have changed, the relative degree of protection provided by the proposed 8-hour standard and the patterns observed across alternative standards are similar to those in the estimates available prior to proposal, and the proposed standard is still estimated to result in important improvements in public health. The supplemental analyses also more clearly show that the proposed 8-hour standard provides a more consistent target for public health protection, given the city-to-city variability observed in air quality patterns, relative to the existing 1-hour standard. It also is important to note that quantitative exposure and risk estimates are just one of many factors the Agency considered in developing the proposal. Other considerations include: (1) evaluation of the scientific evidence for a range of effects, (2) CASAC recommendations and experts' views on alternative standards to protect public health, (3) evaluation of population groups particularly at risk, (4) estimates of exposures of concern, and (5) air quality comparisons for cities upon attaining alternative standards. Thus, while the supplemental analyses estimate somewhat higher peak exposures of concern and lower risks of adverse effects upon attaining the proposed and current standards, they do not substantively change the basis for the proposed standard.

Question 5. Does EPA consider a "biological response" to be the same as an "adverse health effect?"

Answer. No. All individuals frequently experience biological responses to a variety of environmental stresses (e.g., heat, cold, pollens, solar radiation, air pollutants), most of which are sufficiently transient and mild as to not adversely affect an individual's health. Distinguishing between measurable biological responses and adverse health effects is often a central issue in the review of a NAAQS, and was, in fact, a central issue in the current review of the ozone NAAQS.

As discussed in the *Federal Register* preamble (61 FR 65772-65773), in making judgments as to when ozone-related responses become significant enough that they should be regarded as adverse to the health of individuals in sensitive populations, the Administrator has looked to guidelines published by the American Thoracic Society (ATS) and the advice of CASAC. While recognizing that perceptions of "medical significance" and "normal activity" may differ among physicians, lung physiologists, and experimental subjects, the ATS (1985) defined adverse respiratory health effects as "medically significant physiologic or pathologic changes generally evidenced by one or more of the following: (1) interference with the normal activity of the affected person or persons, (2) episodic respiratory illness, (3) incapacitating illness, (4) permanent respiratory injury, and/or (5) progressive respiratory dysfunction."

Application of these guidelines to particular health effects related to ambient ozone (O₃) exposures involves judgments about which medical experts on the CASAC panel and public commenters have expressed a diversity of views. To help frame such judgments, the EPA staff defined gradations of individual functional responses (e.g., decrements in forced expiratory volume in 1 second (FEV₁), increased airway responsiveness) and symptomatic responses (e.g., aggravated cough, chest pain, wheeze), together with judgments as to the potential impact on individuals experiencing varying degrees of severity of these responses. These gradations and impacts, summarized below, are discussed in the Criteria Document (Chapter 9) and Staff Paper (section V.F, Table V-4a, 4b, 4c for individuals with impaired respiratory systems and Table V-5a, 5b, 5c for healthy individuals) and incorporate

significant input from the CASAC panel of medical experts. The CASAC panel expressed a consensus view that the “criteria for the determination of an adverse physiological response was reasonable” (Wolff, 1995b).

More specifically, for individuals with impaired respiratory systems, small functional responses (e.g., FEV₁ decrements of 3 percent to ≤10 percent, increased non-specific bronchial responsiveness <100 percent, lasting less than 4 hours) and/or mild symptomatic responses (e.g., cough with deep breath, discomfort just noticeable on exercise or deep breath, lasting less than 4 hours) would likely interfere with normal activity for relatively few such individuals and would likely result in the use of normal medication as needed. Moderate functional responses (e.g., FEV₁ decrements >10 percent but <20 percent, increased nonspecific bronchial responsiveness ≤300 percent, lasting up to 24 hours) and/or moderate symptomatic responses (frequent spontaneous cough, marked discomfort on exercise or deep breath, wheeze accompanied by shortness of breath, lasting up to 24 hours) would likely interfere with normal activity for many such individuals and would likely result in additional or more frequent use of medication. Large functional responses (e.g., FEV₁ decrements ≥20 percent, increased nonspecific bronchial responsiveness >300 percent, lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, marked wheeze accompanied by shortness of breath, lasting longer than 24 hours) would likely interfere with normal activity for most such individuals and would likely increase the likelihood of seeking medical treatment or visiting an emergency room.

For active healthy individuals, it is judged that moderate levels of functional responses (e.g., FEV₁ decrements >10 percent but >20 percent lasting up to 24 hours) and/or moderate symptomatic responses (e.g., frequent spontaneous cough, marked discomfort on exercise or deep breath, lasting up to 24 hours) would likely interfere with normal activity for relatively few individuals in the at-risk populations of concern (active children and outdoor workers). Further, it is judged that large functional responses (e.g., FEV₁ decrements >20 percent lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, lasting longer than 24 hours) would likely interfere with normal activity for many such individuals.

In judging the extent to which such impacts represent effects that should be regarded as adverse to the health status of individuals, an additional factor that the Administrator has considered is whether such effects are experienced repeatedly by an individual during the course of a year or only on a single occasion. While some experts would judge single occurrences of moderate responses to be a “nuisance,” especially for healthy individuals, a more general consensus that such moderate responses may be adverse emerges as the frequency of occurrence increases. Thus, the Administrator agrees with the judgments presented in the Staff Paper that repeated occurrences of moderate responses, even in otherwise healthy individuals, may be considered to be adverse since they could well set the stage for more serious illness.

Question 6. What specific public health considerations form the basis for your selection of the 8-hour, 80 ppb, 3rd maximum exceedance standard?

Answer. Taken as a whole, the scientific evidence evaluated in the EPA’s Criteria Document and summarized in the Staff Paper indicates that, at levels below the current standard, O₃ affects not only people with impaired respiratory systems, such as asthmatics, but healthy children and adults as well. The consensus of the CASAC Panel was that these documents provide an adequate scientific basis for making regulatory decisions on the standard.

The key controlled human exposure studies identified in this review showed that some moderately exercising healthy individuals exposed for 6 to 8 hours at O₃ levels as low as 0.08 ppm experienced transient health effects such as decreased lung function as measured by FEV₁, respiratory symptoms, and lung inflammation; and lead to concern that these exposures when repeated can lead to long term effects. Summer camp studies also provide extensive and reliable evidence of decreased lung function as measured by FEV₁ in children and adolescents engaged in typical outdoor activities. Other recent studies provide evidence of an association between elevated O₃ levels and increases in hospital admissions and emergency room visits, which signal significantly larger increases in doctor’s visits, school absences, and lost work days. Further, animal studies demonstrate impairment of lung defense mechanisms and suggest that repeated exposure to O₃ over time might lead to permanent structural damage in the lungs, though these effects have not been corroborated in humans.

Based on this evidence, the CASAC Panel was in unanimous agreement that the present 1-hour standard should be eliminated and replaced with an 8-hour standard to focus on those exposures that are of most concern. The CASAC Panel also en-

dorsed the range of 8-hour average concentrations (0.07 to 0.09 ppm) that EPA staff recommended for consideration. Further, the CASAC panel favored changing the form of the standard to one that allowed for multiple exceedances. Thus, CASAC's evaluation of the evidence is consistent with that of EPA, namely that all three major elements of the current O₃ standard should be revised, including the averaging time, the level, and the form.

In reaching a decision on the specific level and form for an 8-hour standard, EPA considered a number of complex and interrelated public health factors. The quantitative assessments of exposures to ozone at levels of concern and of the risk of experiencing various effects indicated differences in public health protection among the various levels and forms considered, but they did not by themselves provide a clear break point for a decision. The quantitative assessments do, however, indicate that, under EPA's proposed standard, there will be hundreds of thousands of times where children will experience fewer incidences of significant decreases in lung function and aggravated respiratory symptoms.

Also, consistent with EPA's prior decisions over the years, when setting an air quality standard for a pollutant for which there is no discernible threshold, factors such as the nature and severity of the health effects involved, and the nature and size of the at-risk populations exposed are important considerations. Thus, EPA paid particular attention to the health-based concerns reflected in the independent scientific advice. The Administrator also gave significant consideration to the advice of the human health professionals on the CASAC Panel. Of the four human health experts on the CASAC Panel, three favored a level of 0.08 ppm and the other favored a level of either 0.08 or 0.09 ppm. No Panel member favored a standard level of 0.07 ppm; three others favored 0.09 ppm, and one favored either 0.09 or 0.10 ppm combined with new public health advisories when O₃ concentrations are at or above 0.07 ppm. Thus, the proposed level of 0.08 ppm reflects the lowest level recommended by individual CASAC members; it also reflects the Administrator's consideration of the recommendations of the human health experts on the CASAC panel; and it is the lowest level tested and shown to cause adverse health effects in controlled human-exposure health studies.

Finally, given the uncertainties associated with this kind of complex health decision, EPA has also looked at the reduction in people exposed to ozone concentrations that are above the highest level recommended by any member of the CASAC panel (i.e., 0.09 ppm). Recent air quality data indicate that meeting a 0.08 ppm third-highest concentration standard (as proposed by EPA) would result in all but 1 percent of areas avoiding days with peak 8-hour concentrations above the 0.09 ppm level. By comparison, a standard set at the upper end of the range of concentrations (5th highest) would result in 17 percent of areas exceeding the 0.09 level.

Question 7. How do the health benefits for the proposed ozone standard compare to the other alternatives for which EPA is taking comment?

Answer. The EPA's risk analyses show that under the proposed standard of 0.08 ppm, there would be hundreds of thousands of times when children will experience fewer incidences of significant decreases in lung function and aggravated respiratory symptoms. While the differences in the percentages of children affected may be small, they represent hundreds of thousands of children. The risk analyses indicate, for example, that compared to meeting the current ozone standard, meeting the proposed ozone standard would reduce the risk of children experiencing over a million significant cases of reduced lung function (i.e., FEV₁≥15 to 20 percent and greater) and hundreds of thousands of respiratory symptoms (e.g., aggravated cough, chest pain). Furthermore, there would be a decreased risk of lung inflammation and hospital admissions for respiratory causes. EPA has identified information compiled by the Centers for Disease Control and the U.S. Department of Health and Human Services, and assessments prepared by New York State (Rowe et al., 1995) and Dr. George Thurston (Thurston et al., 1997) indicating that other related effects such as emergency room visits, doctor visits, lost work days, and school absences would also be reduced. While larger health benefits are estimated for the lower alternative 8-hour standard of 0.07 ppm, the uncertainties in these estimates increase significantly at lower exposure levels, and no CASAC members judged that the additional health benefits estimated for such a standard were a sufficient basis to set a standard at this level.

Question 8. Why does EPA use the decreased lung function of 15 percent FEV and 20 percent FEV as an indicator of adverse health effects? How does that translate into numbers of people likely to suffer health effects such as cough and chest pain?

Answer. As discussed in the response to Question 5, decreased lung function is one of many health endpoints used as an indicator of adverse health effects. De-

creased lung function of 15 percent is the midpoint of the range defined as moderate, and greater than 20 percent (up to 50 percent or more) is defined as large.

There is only a weak association between decreased lung function as measured by FEV decrements and respiratory symptoms, and thus changes in lung functions do not readily translate into numbers of people likely to suffer health effects such as aggravated cough or chest pain. Respiratory symptoms, which can act as early warning signals, do not always accompany decreases in lung functions, particularly in children. Such an absence of symptoms can result in children continuing outdoor activity longer than they would if they experienced such symptoms. This can translate into continued exposure of active children outdoors when ozone levels are high, and potentially can result in greater decreases in lung function, greater risk of repeated lung inflammation, increased risk of hospital admissions and emergency room visits for respiratory causes.

Question 9. Is there a conflict in the time-line between complying with the current and proposed standards for ozone? I understand the OTAG SIP call is scheduled for this summer. How will this be handled? Will there be a similar conflict between current PM standards and those proposed? What type of technical and economic resources will be available to the states?

Answer. At the same time EPA proposed the NAAQS, it also proposed an Interim Implementation Policy. The purpose of this proposed policy is to provide guidance to State and local agencies during the time period between promulgation of any final NAAQS and approval of the State Implementation Plans for revised NAAQS. The principles upon which this policy was based were negotiated with a group of stakeholders (State, industry, and environmental groups) and accepted by the FACA Subcommittee on Integrated Implementation. This proposed policy recognized the existence of OTAG and was structured to include any final OTAG actions. While there is no PM equivalent to OTAG, the policy recognizes the need to continue implementation of the current PM₁₀ program and to coordinate those activities with the proposed development of a PM_{2.5} program.

It should also be noted that there is no conflict between the actions being taken to achieve the current ozone and PM standards and any future actions to achieve the proposed standards. To address the problems of ozone and PM, especially fine PM, it will take a combination of regional and local strategies to reduce air pollution. Regional strategies to reduce nitrogen oxides and sulfur dioxide will help to significantly reduce the background levels of ozone and fine PM. These efforts will bring many nonattainment areas into attainment. For other areas, local control measures on nitrogen oxides, volatile organic compounds, sulfur dioxide, and PM will be necessary to achieve the proposed standards. The exact mix of which pollutants and sources need controls will vary from area to area depending on the nature of the problem in each area.

The OTAG SIP call scheduled for this summer will focus on the regional part of the problem and is critical to the attaining of either the current or the proposed ozone standard. This call is critical to continued progress in cleaning the air as we move to the implementation of any new standards. The same is true for efforts to achieve the current PM₁₀ standard. These efforts are essential to address the coarse fraction of particulate matter, which continues to be of significant concern. Indeed, in some cases, these measures also address the fine PM as well. These actions are not in conflict with achieving any new PM standards. Moreover, they are consistent with achieving the PM₁₀ standards which EPA has proposed to retain in some form.

The EPA has dedicated significant resources to assisting the States and local areas in developing their implementation strategies for achieving the current ozone and PM standards, and we will continue to provide this assistance in the future. In fact, we are pursuing ideas with the FACA Subcommittee on Integrated Implementation to improve and harmonize the efforts of the States and local areas in addressing the regional nature of the ozone and PM problems.

Question 10. How many PM_{2.5} monitors currently are in operation and at what locations? How many additional monitors will be necessary to provide adequate data to designate? How long does EPA anticipate it will take to place monitors and collect adequate data?

Answer. Currently there are approximately 200 sites with operating PM_{2.5} instruments, the majority of which are in the Western US. It has not yet been determined whether or not these monitors will be equivalent to the Federal Reference Method (FRM) monitors. We are currently canvassing the Regions and States to determine the exact number and location of each of these sites. Seventy-two of these PM_{2.5} monitoring sites are operated by the National Park Service with support from EPA and located in National Park and Wilderness areas. It has not yet been determined whether or not these National Park Service monitors will be equivalent to the Fed-

eral Reference Method monitors, since the FRM has just been proposed. Beyond the monitors currently in place, the PM_{2.5} monitoring program is being phased in over a 3-year period with a complete network of approximately 1200 sites expected in the year 2000. We would expect to have significant data on fine particles for several hundred sites by the end of 1999. A full 3 years of data for all sites would, of course, not be available until the end of 2002.

Question 11. On what peer-reviewed research does EPA base its selection of 50 $\mu\text{g}/\text{m}^3$ and 15 $\mu\text{g}/\text{m}^3$?

Answer. In developing proposed PM_{2.5} standards, the Administrator believed that the suite of standards could be most effectively and efficiently defined by treating the annual standard as the generally controlling standard for lowering both short- and long-term PM_{2.5} concentrations. Therefore the full range of short- and long-term community epidemiological studies of the health effects of particulate matter were considered in developing the proposed annual standard. Of the more than 80 such studies identified in the Criteria Document and Staff Paper, the Administrator placed greatest weight on those epidemiological studies reporting associations between health effects and direct measures of fine particles, most notably those recent studies conducted in North America. As noted in the preamble (61 FR 65660), the studies most directly useful in selecting the levels of the annual and 24-hour PM_{2.5} standards are those studies specifically reporting significant associations between adverse health effects and PM_{2.5} which are included in Tables V-12 and V-13 of the Staff Paper (attached). Not only were all of these studies subjected to peer review in the scientific literature, but EPA's assessments of these studies in the Criteria Document and Staff Paper were also subjected to additional expert peer review by CASAC as well as public review.

The proposed level of 15 $\mu\text{g}/\text{m}^3$ for the annual PM_{2.5} standard reflects primarily (1) the evidence from studies in which fine particles were directly measured showing serious health effects at levels below those allowed by the current standard; (2) the recognition that while no thresholds have been discerned, uncertainties in the evidence of effects increase markedly as the PM concentrations decrease; (3) the annual mean concentrations in cities in which serious health effects are associated with short-term exposures range from about 16 to 21 $\mu\text{g}/\text{m}^3$; and (4) the annual means in cities in which serious health effects are associated with long-term exposures, which in one study average about 18 $\mu\text{g}/\text{m}^3$, with increased risk being suggested by the data at annual means of about 15 $\mu\text{g}/\text{m}^3$.

Consistent with the rationale outlined above, the proposed 24-hour standard is intended as a "backstop" to protect against extremely high peak days, localized "hot spots," and risks arising from seasonal emissions not adequately controlled by an annual standard. The proposed level of 50 $\mu\text{g}/\text{m}^3$ for the 24-hour PM_{2.5} standard reflects primarily (1) consideration of the combined effects of both PM_{2.5} standards; (2) the importance of protecting against peak short-term exposures that might not be controlled by the proposed annual standard; and (3) 24-hour concentrations (98th percentile values) in cities in which serious health effects are associated with short-term exposures to fine particles range from about 35 to 90 $\mu\text{g}/\text{m}^3$, with most above 40 to above 50 $\mu\text{g}/\text{m}^3$.

Question 12. On what specific projected health benefits does EPA base its selection of a 24-hour standard of 50 $\mu\text{g}/\text{m}^3$? Its selection of an annual standard of 15 $\mu\text{g}/\text{m}^3$?

Answer. For the particulate matter standard review, EPA assessed hundreds of peer reviewed scientific research studies, including numerous community-based epidemiological studies. Many of these community-based health studies show associations between particulate matter and serious health effects. These include premature death of elderly people or others with heart and/or respiratory problems each year. Other health effects associated with exposure to particles include aggravation of respiratory and cardiovascular disease, including more frequent and serious attacks of asthma in children. The results of these health effects have been significantly increased numbers of missed work and school days, as well as increased hospital visits, illnesses, and other respiratory problems.

The EPA's risk assessment produced quantitative estimates of the potential benefits of attaining the proposed standards in two cities. These risk assessments provided useful insights in selecting the averaging times, forms, and levels of the proposed standards, particularly in regard to weighing the uncertainties in potential benefits for standards at lower concentrations. However, as outlined in response to Question 11 above, the proposed standard levels were based on a consideration of the health effects literature, and not on estimated national benefits associated with alternative standard levels.

The EPA has, however, calculated a potential range of projected incremental benefits for partial implementation of the proposed PM_{2.5} standards for the Regulatory Impact Analysis. These analyses indicate that the incremental benefits of the proposed PM_{2.5} standards—over both the current PM₁₀ standards and full implementation of the Clean Air Act Amendment requirements—would include health improvements ranging as high as tens of thousands fewer premature deaths each year, about ten thousand fewer respiratory-related hospital admissions each year, hundreds of thousands fewer incidences each year of aggravated asthma and respiratory symptoms, and tens of thousands fewer cases each year of chronic bronchitis.

Question 13. Does the Federal Government have to comply with SIPs—especially with regard to particulate matter—when it undertakes prescribed burns? How about with its wildfire management program?

Answer. Section 176 of the Act requires that the activities of Federal agencies, such as prescribed burns, conform to approved SIPs. A Federal agency conforms to a SIP when it adheres to the SIP's purpose of eliminating or reducing the severity and number of violations of the NAAQS, when it does not delay timely attainment of the NAAQS, and when it does not cause or contribute to any new violations in any area. Federal agencies can conform to SIPs by working with State air regulatory agencies to include projected PM emissions from their prescribed burn plans in the SIP.

Wildfires are by definition unplanned, unwanted fires that require appropriate suppression. The act of suppressing a wildfire and its smoke (PM emissions) is basically conforming to a SIP's purpose. Furthermore, EPA issued a policy statement on May 30, 1996 regarding areas affected by natural events such as wildfires. A copy of the policy is attached. The policy allows states to discount PM₁₀ air quality data that results from natural events in certain circumstances provided that a plan is implemented to increase public awareness and minimize the health impacts of such events.

Question 14. What is the historic role of the scientific community in the NAAQS review process? In addition to the CASAC process, how does the scientific community interact with EPA to set the standards?

Answer. The scientific community has historically played a key role in the NAAQS review process. The first step in the process is an extensive scientific and technical assessment which includes developing a "Criteria Document" reflecting the latest scientific knowledge on the kind and extent of all identifiable effects of the pollutant on public health or welfare. This Criteria Document draws entirely on the research conducted by the scientific community and published in the peer-reviewed scientific literature. Building on the evaluation of this literature in the Criteria Document is a further detailed scientific and technical assessment, known as a "Staff Paper." The Staff Paper identifies and evaluates the implications for decisionmaking of the key information in the Criteria Document; it also arrays a range of alternatives based on the scientific evidence and makes recommendations to the Administrator. As discussed below, both of these documents go through extensive public and external scientific peer review.

Criteria Documents are comprehensive assessments that typically examine thousands of studies that have been published in peer review journals. Teams of scientific experts both within and outside EPA prepare draft chapters of a Criteria Document based on exhaustive reviews of the relevant scientific literature. The EPA then holds a series of national and international peer review workshops at which other scientific experts review the draft chapters and suggest appropriate revisions. Once the entire document has been completed in draft form, it is further reviewed by the public and by CASAC. Established by Congress specifically to advise EPA on review and revision of NAAQS, the CASAC is a panel of independent science experts external to EPA. During the review for each air pollutant, the CASAC panel is augmented with additional scientific and technical consultants who have expertise related to that pollutant and its effects. In total, there were 21 scientists and technical experts from academia, research institutes, public health organizations and industry who were on the CASAC review panel for the particulate matter Criteria Document and Staff Paper and 16 who were on the CASAC review panel for the ozone Criteria Document and Staff Paper.

The CASAC panel reviews the draft Criteria Document and the key underlying studies and makes recommendations for revisions to the Criteria Document. Scientists and other representatives from industry, State and local agencies, and members of the public also submit extensive comments on the draft Criteria Documents. EPA revises the document and submits it for another review by the CASAC and the public. This process is often repeated two or three times until the CASAC sends EPA what is known as a "closure" letter, indicating that the Criteria Document pro-

vides an adequate basis for a decision on whether or not a given standard should be revised.

Staff Papers identify the most policy-relevant information contained in the Criteria Document and the critical elements that the EPA staff believes should be considered in the review of the standards. The Staff Paper typically includes quantitative exposure and risk analyses. This document also includes staff recommendations of ranges of alternative standards that the staff believes should be considered in any Agency decision on revising a standard. Like the Criteria Document, this draft Staff Paper is subject to review by the public and the CASAC panel. And like the Criteria Document, the Staff Paper often undergoes two or more reviews—where the scientific panel recommends changes and EPA responds to those recommendations—before the CASAC issues a letter of “closure” on it as well. At that point the Staff Paper, along with the Criteria Document, is used as the basis for Agency decisions as to whether it is appropriate to propose any revisions to the standards. Scientists from other Federal agencies also provide review and comment to EPA prior to the publication of proposed decisions.

During the public comment period on the proposed decisions, the scientific community as well as private citizens and other affected groups, such as members of industry and State and local regulatory agencies, have the opportunity to provide EPA with their views on the proposal. EPA has gone to unprecedented lengths to encourage and facilitate comments through numerous public meetings and hearings, national satellite broadcasts, and toll-free telephone hotlines and special E-mail addresses. EPA reviews and considers comments from the scientific community and the public before reaching a final decision. A notice of the final decision is then prepared.

Question 15. EPA received an appropriation [of] \$18.8 million for PM research. What is the status of that research?

Answer. Using 1997 PM research resources (a total of \$19,051,400 and 89.0 work years), EPA is continuing and expanding efforts to:

- “understand the potential health effects associated with fine PM;”
- focus on field studies and methods used to better characterize the airborne fine particles people are exposed to in major regions of the country and produce the means to model and measure them;
- analyze new statistical and epidemiological PM studies to determine their relevance to the PM NAAQS, which will either facilitate application of the current PM NAAQS or improve the data base for the next PM NAAQS update;
- allow for accurate estimates of emission rates from fugitive, stationary, and mobile sources by understanding the specific composition of the constituents emitted and improving techniques to prevent or capture particles of all sizes, which will allow for successful implementation of current and future PM NAAQS; and
- provide consultation and support so risk assessments by state, Regional, and international air pollution control offices will be done with less uncertainty.

Question 16. Seventeen of the 21 CASAC PM panel members voted to “close” on the PM Staff Paper. Has CASAC used this term consistently throughout its history of reviewing NAAQS? What is the accepted meaning of the term closure? In addition, the panel voted strongly in support of establishing a standard to control PM_{2.5}. Is it unusual for CASAC to call for more research? Is this call for more research inconsistent with CASAC’s advise to establish a PM_{2.5} standard? Does EPA need more time to conduct further research before setting new standards?

Answer. In a report of the CASAC (“Setting Ambient Air Quality Standards: Improving the Process,” September 1981), the Criteria Document closure process was described:

Closure represents a sense of the committee determination upon the scientific adequacy of a Criteria Document for regulatory purposes at a specific point in time, based upon the information currently available. Closure is intended to supplement other forms of channeling advice such as transcripts, individual notes, and official committee minutes. The overall purpose of closure, therefore, is to ensure that the committee has given explicit written advice concerning a Criteria Document so that in the future the committee’s position will not be misunderstood. Embodied within the concept of closure is that, when necessary, individual committee members can submit written minority reports if they disagree with all or part of the full committee report. A sense of the committee report would be signed by the chairman.

With specific regard to the particulate matter review, the closure letter to the Administrator for the PM Staff Paper, dated June 13, 1996, noted that although our understanding of the health effects of PM is far from complete, the Staff Paper provides “an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards.”

When CASAC reviewed the Staff Paper, 19 out of 21 panel members recommended establishment of new standards (daily and/or annual) for PM_{2.5}. They also agreed with the retention of the current annual PM₁₀ standards and consideration of retention of the 24-hour PM₁₀ standard in a more stable form. The EPA's proposal to add new standards for PM_{2.5}, based on public health considerations, is consistent with the advice of the CASAC scientists.

There is no inconsistency in recommending action to protect public health in light of the most recent comprehensive assessment of the available scientific information, while at the same time calling for substantial resources to improve our scientific understanding for future reviews. It indeed has been the practice of the CASAC and the Agency to develop research needs at the conclusion of each criteria and standards review. This responsible public health policy and research approach flows directly from the requirements of the Clean Air Act. The Act directs EPA to establish standards that protect public health with an adequate margin of safety, based on the most recent scientific criteria. These criteria are to address air pollution that "may reasonably be anticipated to endanger public health." Yet the Act also requires that the criteria and standards be reviewed every 5 years. If Congress intended that standards be established only after all appropriate scientific research had been completed and all significant uncertainties addressed, there would be no need for these periodic reviews to update the science.

In the case of particulate matter, the Administrator has responded to the health risks revealed in the most recent scientific assessment by proposing new standards for fine particles, while pursuing a vigorous research program to reduce the scientific uncertainties. She believes that this reflects a prudent and responsible public health policy that is soundly based on the available scientific information. This approach is strongly supported by the Agency's science advisors. Clearly the strongest consensus from the CASAC was in their near-unanimous support for maintaining PM₁₀ standards and establishing new standards for PM_{2.5}, and for mounting a comprehensive research program to improve our scientific understanding of the key issues.

It will take several years to put an implementation program in place for any new standards. The effort to conduct monitoring and develop control programs will undoubtedly reveal additional scientific and technical information needs. The research done over the next few years could be of significant benefit in improving these ongoing programs, as well as improving the quality of the next criteria and standards review. A delay in establishing these standards would add several years to the time when significant health benefits can be realized, resulting in potentially tens of thousands of additional premature deaths and even larger numbers of individuals with air pollution related illness and symptoms.

Question 17. What is the division of costs between State and Federal Government and private industry?

Answer. Governmental costs were not separately estimated in EPA's Regulatory Impact Analyses (RIAs). EPA believes, however, that it is reasonable to expect that the share of control costs borne by private industry will be considerably larger than those borne by the state and Federal Governments. Administrative costs were not assessed in the initial RIAs, and thus, a detailed breakout of these costs is not available. Administrative costs, however, are expected to be only a small fraction of total implementation costs. Administrative cost estimates will be provided in the revised RIAs to be completed in July 1997.

Question 18. Did EPA consider the benefits associated with any reduction in health care costs as a result of implementation of the proposed standards?

Answer. No. Costs and monetized benefits are not considered by EPA in developing the proposed primary standards. The EPA based its proposed decisions on the ozone and particulate matter standards on a thorough review, in the Criteria Document, of the latest scientific information on known and potential human health effects associated with exposure to these pollutants at levels typically found in the ambient air. These decisions also take into account the Staff Paper assessments, including risk and exposure analyses, CASAC advice and recommendations, and public comments received during the development of these documents. In general, the best scientific studies for these pollutants presented health benefits in terms of the effects themselves, and not on health costs avoided.

However, pursuant to Executive Order 12866, the Agency performed Regulatory Impact Analyses (RIA) which calculated the health benefits associated with the proposed standards. Numerous health benefit categories were quantified in the RIA including health care cost savings from reduced hospital admissions.

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR
LIEBERMAN

Question 1. What is your basis for selecting the levels for the particulate matter daily and annual proposed standards?

Answer. In developing proposed PM_{2.5} standards, the Administrator believed that the suite of standards could be most effectively and efficiently defined by treating the annual standard as the generally controlling standard for lowering both short- and long-term PM_{2.5} concentrations. Therefore the full range of short- and long-term community epidemiological studies of the health effects of particulate matter were considered in developing the proposed annual standard. Of the more than 80 such studies identified in the Criteria Document and Staff Paper, the Administrator placed greatest weight on those epidemiological studies reporting associations between health effects and direct measures of fine particles, most notably those recent studies conducted in North America. As noted in the preamble (61 FR 65660), the studies most directly useful in selecting the levels of the annual and 24-hour standards are summarized in Tables V-12 and V-13 of the Staff Paper (attached). Not only were all of these studies subjected to peer review in the scientific literature, but EPA's assessments of these studies in the Criteria Document and Staff Paper were also subjected to additional expert peer review by CASAC as well as public review.

The proposed level of 15 µg/m³ for the annual PM_{2.5} standard reflects primarily (1) the evidence from studies in which fine particles were directly measured showing serious health effects at levels below those allowed by the current standard; (2) the recognition that while no thresholds have been discerned, uncertainties in the evidence of effects increase markedly as the PM concentrations decrease; (3) the annual mean concentrations in cities in which serious health effects are associated with short-term exposures range from about 16 to 21 µg/m³; and (4) the annual means in cities in which serious health effects are associated with long-term exposures, which in one study average about 18 µg/m³, with increased risk being suggested by the data at annual means of about 15 µg/m³.

Consistent with the rationale outlined above, the proposed 24-hour standard is intended as a "backstop" to protect against extremely high peak days, localized "hot spots," and risks arising from seasonal emissions not adequately controlled by an annual standard. The proposed level of 50 µg/m³ for the 24-hour PM_{2.5} standard reflects primarily (1) consideration of the combined effects of both PM_{2.5} standards; (2) the importance of protecting against peak short-term exposures that might not be controlled by the proposed annual standard; and (3) 24-hour concentrations (98th percentile values) in cities in which serious health effects are associated with short-term exposures to fine particles range from about 35 to 90 µg/m³, with most above 40 to 50 µg/m³.

Question 2. What is your basis for selecting an ozone standard at 0.08 ppm with three exceedances, rather than a 0.07 or 0.09 ppm standard?

Answer. Taken as a whole, the scientific evidence evaluated in the EPA's Criteria Document and summarized in the Staff Paper indicates that, at levels below the current standard, O₃ affects not only people with impaired respiratory systems, such as asthmatics, but healthy children and adults as well. The consensus of the CASAC Panel was that these documents provide an adequate scientific basis for making regulatory decisions on the standard.

The key controlled human exposure studies identified in this review showed that some moderately exercising healthy individuals exposed for 6 to 8 hours at O₃ levels as low as 0.08 ppm experienced transient health effects such as decreased lung function as measured by FEV₁, respiratory symptoms, and lung inflammation; and lead to concern that these exposures when repeated can lead to long term effects. Summer camp studies also provide extensive and reliable evidence of decreased lung function as measured by FEV₁ in children and adolescents engaged in typical outdoor activities. Other recent studies provide evidence of an association between elevated O₃ levels and increases in hospital admissions and emergency room visits, which signal significantly larger increases in doctor's visits, school absences, and lost work days. Further, animal studies demonstrate impairment of lung defense mechanisms and suggest that repeated exposure to O₃ over time might lead to permanent structural damage in the lungs, though these effects have not been corroborated in humans.

Based on this evidence, the CASAC Panel was in unanimous agreement that the present 1-hour standard should be eliminated and replaced with an 8-hour standard to focus on those exposures that are of most concern. The CASAC Panel also viewed as appropriate the range of 8-hour average concentrations (0.07 to 0.09 ppm) that EPA recommended for consideration. Further, the CASAC panel favored changing

the form of the standard to one that allowed for multiple exceedances. Thus, CASAC's evaluation of the evidence is consistent with that of EPA, namely that all three major elements of the current O₃ standard should be revised, including the averaging time, the level, and the form.

In reaching a decision on the specific level and form for an 8-hour standard, EPA considered a number of complex public health factors. The quantitative assessments of exposures to levels of concern and of the risk of experiencing various effects indicated differences in public health protection among the various levels and forms considered, but they did not by themselves provide a clear break point for a decision. The quantitative assessments do, however, indicate that, under EPA's proposed standard, there will be hundreds of thousands of times when children will experience fewer incidences of significant decreases in lung function and aggravated respiratory symptoms.

Also, consistent with EPA's prior decisions over the years, when setting an air quality standard for a pollutant for which there is no discernible threshold, factors such as the nature and severity of the health effects involved, and the nature and size of the at-risk populations exposed are important considerations. Thus, EPA paid particular attention to the health-based concerns reflected in the independent scientific advice. The Administrator also gave significant consideration to the advice of the human health professionals on the CASAC Panel. Of the four human health experts on the CASAC Panel, three favored a level of 0.08 ppm and the other favored a level of either 0.08 or 0.09 ppm. No Panel member favored a standard level of 0.07 ppm; three others favored 0.09 ppm, and one favored either 0.09 or 0.10 ppm combined with new public health advisories when O₃ concentrations are at or above 0.07 ppm. Thus, the proposed level of 0.08 ppm reflects the lowest level recommended by individual CASAC members; it also reflects the Administrator's consideration of the recommendations of the human health experts on the CASAC Panel; and it is the lowest level tested and shown to cause adverse health effects in controlled human-exposure health studies.

Finally, given the uncertainties associated with this kind of complex health decision, EPA has also looked at the reduction in people exposed to ozone concentrations that are above the highest level recommended by any member of the CASAC panel (i.e., 0.09 ppm). Recent air quality data indicate that meeting a 0.08 ppm third-highest concentration standard (as proposed by EPA) would result in all but 1 percent of areas avoiding days with peak 8-hour concentrations above the 0.09 ppm level. By comparison, a standard set at the upper end of the range of concentrations (5th highest) would result in 17 percent of areas exceeding the 0.09 level.

Question 3. EPA's Regulatory Impact Analysis (RIA) for ozone included only the most rudimentary treatment of innovative regional and market-based strategies that likely would provide cost-effective approaches to meet the new standard. For particulate matter the RIA did not include any of these flexible approaches. Were the results of the Ozone Transport Commission included in the ozone RIA? Why weren't these types of innovative strategies considered to a greater extent in the RIAs for both pollutants?

Answer. The November 1996 ozone and particulate matter RIAs provided a limited assessment of regional and market-based strategies. The ozone RIA assessed the impacts associated with a regional NO_x cap on utility and large industrial boiler emissions as well as a national low emission vehicle program. This strategy was originally proposed by the Ozone Transport Commission. It was employed in the ozone RIA on a broad geographic scale as a reasonable proxy for a future regional NO_x implementation strategy. The particulate matter RIA assessed the impact of a regional SO_x cap strategy, but only in a sensitivity analysis.

A more complete assessment of regional and market-based strategies was not performed because of uncertainties regarding the specific implementation strategies that may be employed to attain the proposed new standards and because of modeling limitations. It should be noted, however, that even under the current standards, the Agency has begun to emphasize strategies that use the marketplace to reduce costs, that utilize national strategies where they make sense, and that look to regional and other cooperative approaches, so as to maximize efficiencies and minimize costs throughout the air quality management system. Specific to the new standards, EPA has established a formal advisory subcommittee under the Federal Advisory Committee Act to develop innovative, flexible, practical and cost-effective implementation strategies. This FACA Subcommittee operates under the CAAAC, EPA will consider any recommendations received through this process in proposing specific implementation strategies. Future RIAs will assess these proposed regional and market-based strategies in detail. To the extent that more cost-effective imple-

mentation strategies will be identified, the cost estimates for partial attainment presented in the November 1996 ozone and PM RIAs may be overstated.

Question 4. One concern that has been expressed is that implementing a proposed new ozone standard could have a negative effect on making progress under the Clean Air Act. In other words, some contend that the current structure may be thrown into some disarray because areas will spend time planning rather than accomplishing emission reductions. What is your reaction to these concerns? Will any of the work now being done by the Ozone Transport Commission on developing region-wide strategies to control pollution be put on hold by the new standards?

Answer. The Administrator shares the concerns that we not sacrifice continued progress in reducing ozone as we move forward to implement any new standards. It is for this reason that EPA has conditioned the revocation of the current ozone standard for an existing nonattainment area on its determination that each State Implementation Plan provides for the achievement of a new standard. In addition, EPA has proposed a policy to ensure that the progress made in the current program continues until the effective date of EPA approval of an area's SIP to attain the new NAAQS. The efforts currently underway throughout the country, including in the OTC and the Ozone Transport Assessment Group (OTAG), to achieve the current ozone standard support achievement of the proposed standard. Therefore, there is no reason for delays in implementing the measures already planned by States or measures that will be identified shortly through the OTAG work. The OTAG will be recommending regional control strategies in the next few months. In order to support OTAG and ensure the necessary regional reductions will be implemented, EPA intends to issue SIP calls within a specified timeframe to the relevant States. These actions will ensure that we continue to make progress in cleaning the air as we move forward in developing implementation strategies for any new standards. In fact, the regional emission reductions will pay benefits in terms of improved air quality to many local areas and may be the only reductions they need to achieve the proposed standards.

Question 5. Is your decision to set PM_{2.5} standards inconsistent with the need for further research in the area of health effects of particulate matter and with EPA's research agenda in this area?

Answer. Taking action to protect public health in light of the most recent scientific information available is not inconsistent with earmarking substantial resources to improve our scientific understanding for future reviews. Indeed, this responsible public health policy and research approach flows directly from the requirements of the Clean Air Act. The Act directs EPA to establish standards that protect public health with an adequate margin of safety, based on the most recent scientific criteria. These criteria address air pollution that "may reasonably be anticipated to endanger public health." Yet the Act also requires that the criteria and standards be reviewed every 5 years. If Congress intended that standards should only be established after all appropriate scientific research had been completed and all significant uncertainties addressed, there would be no need for these periodic reviews to update the science.

In the case of particulate matter, the Administrator has responded to the health risks revealed in the most recent scientific assessment by recommended establishing new standards for fine particles, while pursuing a vigorous research program to reduce the scientific uncertainties. She believes that this reflects a prudent and responsible public health policy that is soundly based on the available scientific information. This approach is strongly supported by the Agency's science advisors. Clearly the strongest consensus from the CASAC was in support of maintaining PM₁₀ standards and establishing new standards for PM_{2.5} and for mounting a comprehensive research program.

While the research done over the next few years will improve the quality of the next criteria and standards review, a delay in establishing new standards would add several years to the time when significant health benefits can be realized, resulting in potentially tens of thousands of additional premature deaths and even larger numbers of individuals with air pollution related illness and symptoms. EPA believes that moving simultaneously on both health protection and research is the most appropriate approach, one that is consistent with both the philosophy and practice of establishing ambient standards under the Clean Air Act.

Question 6. In our last hearing, we heard testimony suggesting that EPA should first identify the component of particulate matter that is causing the problem before proposing a new standard for fine particulates. Some witnesses suggested that we might pursue the wrong control strategies if we do not wait for this information. Please comment on these concerns.

Answer. The question of which pollutant components to regulate has been a significant concern for particulate matter since the inception of the first particulate matter controls. Other ambient pollutants (e.g., nitrogen dioxide or carbon monoxide) are uniquely defined as individual chemicals, whether or not they serve as proxies for a larger class of substances (e.g., ozone as an index of photochemical oxidants). The act of defining general particulate matter as a regulated pollutant raises the spectrum of a host of particulate materials of varying composition, size, and other physicochemical properties, not all of which are likely to produce identical effects.

Nevertheless, both our past and present regulatory experience with particulate matter controls and each successive review of the standards has resulted in a reaffirmation of the appropriateness of retaining standards that control particles as a group, rather than eliminating such standards and waiting for scientific research to develop information needed to identify more precise limits for the literally thousands of particle components that might or might not be responsible for observed health effects. Each such decision recognized the possibility that potentially less harmful particles might be included in the mix that was regulated, but concluded that the known or anticipated health and environmental benefits of controlling general particles was of paramount concern.

The governmental response to one of the first great air pollution disasters, the 1952 London episode, is instructive. Although scientists did not (and still do not) know the mechanisms by which thousands of individuals died nor which particulate and gaseous pollutants were most likely responsible, a program to reduce the use of "smoky" coal was instituted that, by all accounts, was a success in greatly reducing the impact of air pollution on health. The government also embarked on research to study these effects, which ultimately revealed that effects could occur at much lower concentrations.

These British studies formed the principal basis of the original U.S. particulate matter standards. Each CASAC review of these standards (Friedlander, 1982; Lippmann, 1986; Wolff, 1996) has recognized the continued need to control "general" particulate matter. The major refinements that have been recommended through the course of these reviews have been to improve the measurement of particulate matter by defining scientifically based size classes (i.e., moving from TSP to PM_{10} and $PM_{2.5}$) that permit more effective and efficient regulation of those fractions most likely to present significant risks to health and the environment.

During the most recent review, EPA examined the available data to determine whether the available evidence would tend to support inclusion or exclusion of any other physical or chemical classes of particulate matter, for example sulfates, nitrates, or ultra-fine particles. This review concluded, with CASAC agreement, that the available data continue to support the retention of PM_{10} as a measure of particulate matter. Further, based on an examination of the risk posed by the components of PM_{10} , the Criteria Document concluded it would be most appropriate to "consider fine and coarse mode particles as separate subclasses of pollutants." (U.S. EPA, 1996a, p. 13-94). The examination of component classes found that, while both fine and coarse particles can produce health effects, the fine fraction appears to contain more of the substances potentially linked to the kinds of effects observed in the recent epidemiological studies. However, the available scientific information does not rule out any one of these components as contributing to fine particle effects. Indeed, it is reasonable to anticipate that no single component will prove to be responsible for all of the effects of particulate matter. The consistent epidemiological findings across geographical areas (and particulate composition) supports this view. Nineteen of twenty-one CASAC members agreed with the EPA staff recommendation to add standards for $PM_{2.5}$ as a separate pollutant class.

Whether the standards are set for PM_{10} only or also include $PM_{2.5}$, there are unavoidable uncertainties at present with respect to the relative risk presented by various components of particulate matter. In this regard, the Administrator places greater weight on the concern that by failing to act now, we would not be controlling adequately those components of air pollution that are responsible for adverse effects than on the possibility we might also be controlling some component that may not be related to such effects. $PM_{2.5}$ encompasses all of the potential agents of concern in the fine fraction, including sulfates, acids, transition metals, organics, and ultrafine particles, and includes most of the aggregate surface area and particle number in the entire distribution of atmospheric particles. Subject to consideration of public comments, the Administrator believes that movement to develop control programs for fine particles at this time would clearly serve to reduce the risk of those particle components most likely to present significant health risks.

Question 7. Please discuss the activities of the Federal advisory committee that is helping EPA devise cost-effective ways to implement the proposed standards. Is the committee considering market-based solutions where appropriate?

Answer. The FACA Subcommittee for the Integrated Implementation of the Ozone and PM NAAQS and the Regional Haze Program was established in September 1995. Since that time the Subcommittee has held public meetings approximately every 2 months. There are six workgroups under the Subcommittee which meet on a more frequent basis. The Subcommittee currently consists of about 75 members and is intended to have balanced representation from State and local agencies, tribal organizations, environmental groups, industry, lawyers/consultants, scientific/academic institutions and other Federal agencies. EPA recently took steps to increase the membership of the Subcommittee with particular emphasis on adding additional representatives from small businesses.

The EPA's charge to the Subcommittee was to address innovative, cost effective, and creative approaches when making recommendations on ways to implement new/ revised ozone and PM NAAQS. While costs are not considered in the standard setting process, they are being examined in the development of programs to implement new or revised standards. In the development of these programs, control strategies can be harmonized to take advantage of multi-pollutant control technologies as well as the efficiency of implementing all necessary controls at one time. Additionally, the Subcommittee is examining market-based emissions trading and other economic incentive approaches for achieving emission reductions at a lower overall cost to the economy. These approaches are currently being discussed by the Subcommittee as part of the Phase II strategy in the coming year. Phase II of the implementation strategy, which will address control strategies, including market-based programs and economic incentives, is currently scheduled for proposal in mid-1998.

Question 8. Another concern that has been expressed about the new PM_{2.5} standard and the change in the form of the PM₁₀ standard is that some of the control strategies implemented for PM₁₀ during the last several years will be wasted. What is your response to this criticism?

Answer. The EPA is soliciting public comment on whether to revise the form of the PM₁₀ standard to a more robust form, as recommended by EPA staff and some CASAC members. If the Administrator were ultimately to choose that course, we do not believe that actions taken to date to implement the current standard would be wasted. EPA's current proposal continues the evolution of PM regulation toward more effective and efficient protection of public health. As noted in the response to Question 6 above, the last time PM standards were revised, in 1987, EPA replaced its PM standards measured in terms of "total suspended particulate matter" (TSP) with PM₁₀ standards that excluded particles larger than 10 micrometers. This change improved health protection afforded by PM standards, but did not invalidate the benefits afforded by implementing the previous TSP standards. Indeed, EPA's recent draft study of costs and benefits of the Clean Air Act found billions of dollars of benefits from implementing the former TSP standards. Similarly, EPA believes the addition of PM_{2.5} standards will increase the overall health and welfare protection provided by the particulate matter standards with respect to fine particles. In this case, however, EPA and CASAC both concluded that control of larger PM₁₀ particles (termed "coarse fraction particles") should continue and remains essential to protecting public health.

The nature of the controls needed to meet PM₁₀ and PM_{2.5} standards varies from region to region. For many non-attainment areas in California and the Pacific Northwest, for example, the PM₁₀ standards have prompted significant fine particle control by addressing woodsmoke and photochemically derived particles that are significant contributors to PM₁₀. Clearly, such controls would continue to be needed under the proposed new PM_{2.5} standards. In a number of areas, control of industrial sources to meet the PM₁₀ standards have reduced both fine and coarse particles and would continue. Under EPA's proposed revisions, the need for additional controls in some areas significantly affected by short-term excursions of naturally derived coarse particles (e.g., unpaved roads, dust storms) could be reduced, consistent with EPA's assessment of the health effects evidence. EPA believes, however, that the vast majority of controls put into place under the current PM₁₀ standards have produced significant public health and welfare benefits, and would continue to do so under the proposed shift toward fine particle standards. EPA believes that the proposed revised standards will, however, provide significant additional benefits by focusing additional controls on fine particles that are the source of significant PM exposures in large regions of the Eastern U.S. that are attaining the current standards.

[Attachments to Question 1 from Senator Lieberman follow.]

TABLE V-12. FINE PARTICLE INDICATOR (PM_{2.5}, SO₂, H⁺) EFFECTS STUDIES FROM THE U.S. AND CANADA (CD, Tables 13-4, 12-2, 12-13)

	Indicator	RR (± CI) per 25 µg/m ³ PM Increase	PM Levels Mean (Min/Max) ^f
Acute Mortality			
Six City ^a			
Portage, WI	PM _{2.5}	1.030 (0.993, 1.071)	11.2 (± 7.8)
Topeka, KS	PM _{2.5}	1.020 (0.951, 1.092)	12.2 (± 7.4)
Boston, MA	PM _{2.5}	1.056 (1.038, 1.0711)	15.7 (± 9.2)
St. Louis, MO	PM _{2.5}	1.028 (1.010, 1.043)	18.7 (± 10.5)
Kingston/Knoxville, TN	PM _{2.5}	1.035 (1.005, 1.066)	20.8 (± 9.6)
Steubenville, OH	PM _{2.5}	1.025 (0.998, 1.053)	29.6 (± 21.9)
Increased Hospitalization			
Ontario, CAN ^b	SO ₂	1.03 (1.02, 1.04)	Min/Max = 3.1-8.2
Ontario, CAN ^c	SO ₂	1.03 (1.02, 1.04)	Min/Max = 2.0-7.7
	O ₃	1.03 (1.02, 1.05)	
NYC/Buffalo, NY ^d	SO ₂	1.05 (1.01, 1.10)	NR
Toronto, CAN ^d	H ⁺ (Nmol/m ³)	1.16 (1.03, 1.30)*	28.8 (NR/391)
	SO ₂	1.12 (1.00, 1.24)	7.6 (NR, 48.7)
	PM _{2.5}	1.15 (1.02, 1.78)	18.6 (NR, 66.0)
Increased Respiratory Symptoms			
Southern California ^f	SO ₂	1.48 (1.14, 1.91)	R = 2-37
Six Cities ^g (Cough)	PM _{2.5}	1.19 (1.01, 1.42)**	18.0 (7.2, 37)***
	PM _{2.5} Sulfur	1.23 (0.95, 1.59)**	2.5 (3.1, 61)***
	H ⁺	1.06 (0.87, 1.29)**	18.1 (0.8, 5.9)***
Six Cities ^g (Lower Resp. Symp.)	PM _{2.5}	1.44 (1.15-1.82)**	18.0 (7.2, 37)***
	PM _{2.5} Sulfur	1.82 (1.28-2.59)**	2.5 (0.8, 5.9)***
	H ⁺	1.05 (0.25-1.30)**	18.1 (3.1, 61)***
Denver, CO ^h (Cough, adult asthmatics)	PM _{2.5}	0.0012 (0.0043)****	0.41 - 73
	SO ₂	0.0042 (0.0035)****	0.12 - 12
	H ⁺	0.0076 (0.0038)****	2.0 - 41
Decreased Lung Function			
Uniontown, PA ^e	PM _{2.5}	PEFR 23.1 (-0.3, 36.9) (per 25 µg/m ³)	25/88 (NR/88)
Seattle, WA ^o Asthmatics	b _{max} calibrated by PM _{2.5}	FEV1 42 ml (12,73) FVC 45 ml (20,70)	5/45

TABLE V-13. EFFECT ESTIMATES PER INCREMENTS* IN ANNUAL MEAN LEVELS OF FINE/THORACIC PARTICLE INDICATORS FROM U.S. AND CANADIAN STUDIES (CD, Table 13-5).

Type of Health Effect & Location	Indicator	Change in Health Indicator per Increment in PM ^a	Range of City PM Levels Means ($\mu\text{g}/\text{m}^3$)
Increased total chronic mortality in adults		Relative Risk (95% CI)	
Six City ^b	PM _{15/10}	1.42 (1.16-2.01)	18-47
	PM _{2.5}	1.31 (1.11-1.68)	11-30
	SO ₂ ^c	1.46 (1.16-2.16)	5-13
ACS Study ^c (151 U.S. SMSA)	PM _{2.5}	1.17 (1.09-1.26)	9-34
	SO ₂ ^c	1.10 (1.06-1.16)	4-24
Increased bronchitis in children		Odds Ratio (95% CI)	
Six City ^d	PM _{15/10}	3.26 (1.13, 10.28)	20-59
Six City ^e	TSP	2.80 (1.17, 7.03)	39-114
24 City ^f	H ⁺	2.65 (1.22, 5.74)	6.2-41.0
24 City ^f	SO ₂ ^c	3.02 (1.28, 7.03)	18.1-67.3
24 City ^f	PM _{2.1}	1.97 (0.85, 4.51)	9.1-17.3
24 City ^f	PM ₁₀	3.29 (0.81, 13.62)	22.0-28.6
Southern California ^g	SO ₂ ^c	1.39 (0.99, 1.92)	—
Decreased lung function in children			
Six City ^{d,h}	PM _{15/10}	NS Changes	20-59
Six City ^e	TSP	NS Changes	39-114
24 City ^{i,j}	H ⁺ (52 nmoles/m ³)	-3.45% (-4.87, -2.01) FVC	—
24 City ⁱ	PM _{2.1} (15 $\mu\text{g}/\text{m}^3$)	-3.21% (-4.98, -1.41) FVC	—
24 City ⁱ	SO ₂ ^c (7 $\mu\text{g}/\text{m}^3$)	-3.06% (-4.50, -1.60) FVC	—
24 City ⁱ	PM ₁₀ (17 $\mu\text{g}/\text{m}^3$)	-2.42% (-4.30, -0.51) FVC	—

*Estimates calculated annual-average PM increments assume: a 100 $\mu\text{g}/\text{m}^3$ increase for TSP; a 50 $\mu\text{g}/\text{m}^3$ increase for PM₁₀ and PM₁₅; a 25 $\mu\text{g}/\text{m}^3$ increase for PM_{2.5}; and a 15 $\mu\text{g}/\text{m}^3$ increase for SO₂^c, except where noted otherwise; a 100 nmole/m³ increase for H⁺.

^bDockery et al. (1993)

^cPope et al. (1995)

^dDockery et al. (1989)

^eWare et al. (1986)

^fDockery et al. (1996)

^gAbbey et al. (1995a,b,c)

^hNS Changes = No significant changes.

ⁱRaizenne et al. (1996)

^jPollutant data same as for Dockery et al. (1996)

V-60c

References:

- ^ASchwartz et al. (1996a)
- ^BBurnett et al. (1994)
- ^CBurnett et al. (1995) O₃
- ^DThurston et al. (1992, 1994)
- ^ENeas et al. (1995)
- ^FOstro et al. (1993)
- ^GSchwartz et al. (1994)
- ^HOstro et al. (1991)
- ^IKoenig et al. (1993)

[†]Min/Max 24-h PM indicator level shown in parentheses unless otherwise noted as (\pm S.D.), 10 and 90 percentile (10,90).

^{*}Change per 100 nmoles/m³.

^{**}Change per 20 $\mu\text{g}/\text{m}^3$ for PM_{2.5}; per 5 $\mu\text{g}/\text{m}^3$ for PM_{2.5} sulfur; per 25 nmoles/m³ for H⁺.

^{***}50th percentile value (10,90 percentile).

^{****}Coefficient and SE in parenthesis.

TABLE 13-3. EFFECT ESTIMATES PER 50 $\mu\text{g}/\text{m}^3$ INCREASE
IN 24-h PM_{10} CONCENTRATIONS FROM U.S. AND CANADIAN STUDIES

Study Location	RR (\pm CI) Only PM in Model	RR (\pm CI) Other Pollutants in Model	Reported PM_{10} Levels Mean (Min/Max) [†]
Increased Total Acute Mortality			
<u>Six Cities^a</u>			
Portage, WI	1.04 (0.98, 1.09)	—	18 (\pm 11.7)
Boston, MA	1.06 (1.04, 1.09)	—	24 (\pm 12.8)
Topeka, KS	0.98 (0.90, 1.05)	—	27 (\pm 16.1)
St. Louis, MO	1.03 (1.00, 1.05)	—	31 (\pm 16.2)
Kingston/Knoxville, TN	1.05 (1.00, 1.09)	—	32 (\pm 14.5)
Steubenville, OH	1.05 (1.00, 1.08)	—	46 (\pm 32.3)
St. Louis, MO ^c	1.08 (1.01, 1.12)	1.06 (0.98, 1.15)	28 (1/97)
Kingston, TN ^c	1.09 (0.94, 1.25)	1.09 (0.94, 1.26)	30 (4/67)
Chicago, IL ^h	1.04 (1.00, 1.08)	—	37 (4/365)
Chicago, IL ^g	1.03 (1.02, 1.04)	1.02 (1.01, 1.04)	38 (NR/128)
Utah Valley, UT ^b	1.08 (1.05, 1.11)	1.19 (0.96, 1.47)	47 (11/297)
Birmingham, AL ^d	1.05 (1.01, 1.10)	—	48 (21, 80)
Los Angeles, CA ^f	1.03 (1.00, 1.055)	1.02 (0.99, 1.036)	58(15/177)
Increased Hospital Admissions (for Elderly > 65 yrs.)			
<u>Respiratory Disease</u>			
Toronto, CAN ⁱ	1.23 (1.02, 1.43) [‡]	1.12 (0.88, 1.36) [‡]	30-39 [*]
Tacoma, WA ^j	1.10 (1.03, 1.17)	1.11 (1.02, 1.20)	37 (14, 67)
New Haven, CT ^j	1.06 (1.00, 1.13)	1.07 (1.01, 1.14)	41 (19, 67)
Cleveland, OH ^k	1.06 (1.00, 1.11)	—	43 (19, 72)
Spokane, WA ^l	1.08 (1.04, 1.14)	—	46 (16, 83)
<u>COPD</u>			
Minneapolis, MN ⁿ	1.25 (1.10, 1.44)	—	36 (18, 58)
Birmingham, AL ^m	1.13 (1.04, 1.22)	—	45 (19, 77)
Spokane, WA ^l	1.17 (1.08, 1.27)	—	46 (16, 83)
Detroit, MI ^o	1.10 (1.02, 1.17)	—	48 (22, 82)

TABLE 13-3 (cont'd). EFFECT ESTIMATES PER 50 $\mu\text{g}/\text{m}^3$ INCREASE
IN 24-h PM_{10} CONCENTRATIONS FROM U.S. AND CANADIAN STUDIES

Study Location	RR (\pm CI) Only PM in Model	RR (\pm CI) Other Pollutants in Model	Reported PM_{10} Levels Mean (Min/Max) [†]
<u>Pneumonia</u>			
Minneapolis, MN ^N	1.08 (1.01, 1.15)	—	36 (18,58)
Birmingham, AL ^M	1.09 (1.03, 1.15)	—	45 (19, 77)
Spokane, WA ^L	1.06 (0.98, 1.13)	—	46 (16, 83)
Detroit, MI ^O	—	1.06 (1.02, 1.10)	48 (22, 82)
<u>Ischemic HD</u>			
Detroit, MI ^P	1.02 (1.01, 1.03)	1.02 (1.00, 1.03)	48 (22, 82)
<u>Increased Respiratory Symptoms</u>			
<u>Lower Respiratory</u>			
Six Cities ^Q	2.03 (1.36, 3.04)	Similar RR	30 (13,53)
Utah Valley, UT ^R	1.28 (1.06, 1.56) [‡]	—	46 (11/195)
	1.01 (0.81, 1.27) [‡]		
Utah Valley, UT ^S	1.27 (1.08, 1.49)	—	76 (7/251)
<u>Cough</u>			
Denver, CO ^X	1.09 (0.57, 2.10)	—	22 (0.5/73)
Six Cities ^Q	1.51 (1.12, 2.05)	Similar RR	30 (13, 53)
Utah Valley, UT ^S	1.29 (1.12, 1.48)	—	76 (7/251)
<u>Decrease in Lung Function</u>			
Utah Valley, UT ^R	55 (24, 86) ^{**}	—	46 (11/195)
Utah Valley, UT ^S	30 (10, 50) ^{**}	—	76 (7/251)
Utah Valley, UT ^W	29 (7,51) ^{***}	—	55 (1,181)

References:

^NSchwartz et al. (1996a).
^PPope et al. (1992, 1994)/O₃.
^QDockery et al. (1992)/O₃.
^RSchwartz (1993).
^SIto and Thurston (1996)/O₃.
^TKinney et al. (1995)/O₃, CO.
^USmyer et al. (1995).
^VThurston et al. (1994)/O₃.
^WSchwartz (1995)/SO₂.
^XSchwartz et al. (1996b).

^LSchwartz (1996).
^MSchwartz (1994c).
^NSchwartz (1994f).
^OSchwartz (1994d).
^PSchwartz et al. (1994).
^QSchwartz and Morris (1995)/O₃, CO, SO₂.
^RPope et al. (1991).
^SPope and Dockery (1992).
^TSchwartz (1994g).
^UPope and Kanfer (1993).

^XOstro et al. (1991).
[†]Min/Max 24-h PM_{10} in parentheses unless noted
 otherwise as standard deviation (\pm S.D.), 10 and
 90 percentile (10, 90). NR = not reported.
[‡]Children.
^{*}Asthmatic children and adults.
^{**}Means of several cities.
^{***}PEFR decrease in ml/sec.
^{††}FEV₁ decrease.
^{‡‡}RR refers to total population, not just >65 years.

TABLE 13-4. EFFECT ESTIMATES PER VARIABLE INCREMENTS IN 24-h CONCENTRATIONS OF FINE PARTICLE INDICATORS (PM_{2.5}, SO₄⁻, H⁺) FROM U.S. AND CANADIAN STUDIES

Acute Mortality	Indicator	RR (± CI) per 25 µg/m ³ PM Increase	Reported PM Levels Mean (Min/Max) [†]
Six City^A			
Portage, WI	PM _{2.5}	1.030 (0.993, 1.071)	11.2 (±7.8)
Topeka, KS	PM _{2.5}	1.020 (0.951, 1.092)	12.2 (±7.4)
Boston, MA	PM _{2.5}	1.056 (1.038, 1.0711)	15.7 (±9.2)
St. Louis, MO	PM _{2.5}	1.028 (1.010, 1.043)	18.7 (±10.5)
Kingston/Knoxville, TN	PM _{2.5}	1.035 (1.005, 1.066)	20.8 (±9.6)
Steubenville, OH	PM _{2.5}	1.025 (0.998, 1.053)	29.6 (±21.9)
Increased Hospitalization			
Ontario, CAN ^B	SO ₄ ⁻	1.03 (1.02, 1.04)	R = 3.1-8.2
Ontario, CAN ^C	SO ₄ ⁻	1.03 (1.02, 1.04)	R = 2.0-7.7
	O ₃	1.03 (1.02, 1.05)	
NYC/Buffalo, NY ^D	SO ₄ ⁻	1.05 (1.01, 1.10)	NR
Toronto ^D	H ⁺ (Nmol/m ³)	1.16 (1.03, 1.30) [*]	28.8 (NR/391)
	SO ₄ ⁻	1.12 (1.00, 1.24)	7.6 (NR, 48.7)
	PM _{2.5}	1.15 (1.02, 1.78)	18.6 (NR, 66.0)
Increased Respiratory Symptoms			
Southern California ^F	SO ₄ ⁻	1.48 (1.14, 1.91)	R = 2-37
Six Cities ^G	PM _{2.5}	1.19 (1.01, 1.42) ^{**}	18.0 (7.2, 37) ^{***}
(Cough)	PM _{2.5} Sulfur	1.23 (0.95, 1.59) ^{**}	2.5 (3.1, 61) ^{***}
	H ⁺	1.06 (0.87, 1.29) ^{**}	18.1 (0.8, 5.9) ^{***}
Six Cities ^G	PM _{2.5}	1.44 (1.15-1.82) ^{**}	18.0 (7.2, 37) ^{***}
(Lower Resp. Symp.)	PM _{2.5} Sulfur	1.82 (1.28-2.59) ^{**}	2.5 (0.8, 5.9) ^{***}
	H ⁺	1.05 (0.25-1.30) ^{**}	18.1 (3.1, 61) ^{***}
Decreased Lung Function			
Uniontown, PA ^E	PM _{2.5}	PEFR 23.1 (-0.3, 36.9) (per 25 µg/m ³)	25/88 (NR/88)

References:

^ASchwartz et al. (1996a)^BBurnett et al. (1994)^CBurnett et al. (1995) O₃^DThurston et al. (1992, 1994)^ENeas et al. (1995)^FOstro et al. (1993)^GSchwartz et al. (1994)

[†]Min/Max 24-h PM indicator level shown in parentheses unless otherwise noted as (± S.D.), 10 and 90 percentile (10,90) or R = range of values from min-max, no mean value reported.

^{*}Change per 100 nmoles/m³

^{**}Change per 20 µg/m³ for PM_{2.5}; per 5 µg/m³ for PM_{2.5} sulfur; per 25 nmoles/m³ for H⁺.

^{***}50th percentile value (10,90 percentile)

TABLE 13-5. EFFECT ESTIMATES PER INCREMENTS^a IN ANNUAL MEAN LEVELS OF FINE PARTICLE INDICATORS FROM U.S. AND CANADIAN STUDIES

Type of Health Effect & Location	Indicator	Change in Health Indicator per Increment in PM ^a	Range of City PM Levels Means ($\mu\text{g}/\text{m}^3$)
Increased total chronic mortality in adults		Relative Risk (95% CI)	
Six City ^b	PM _{15/10}	1.42 (1.16-2.01)	18-47
	PM _{2.5}	1.31 (1.11-1.68)	11-30
	SO ₄ ⁻	1.46 (1.16-2.16)	5-13
ACS Study ^c (151 U.S. SMSA)	PM _{2.5}	1.17 (1.09-1.26)	9-34
	SO ₄ ⁻	1.10 (1.06-1.16)	4-24
Increased bronchitis in children		Odds Ratio (95% CI)	
Six City ^d	PM _{15/10}	3.26 (1.13, 10.28)	20-59
Six City ^e	TSP	2.80 (1.17, 7.03)	39-114
24 City ^f	H ⁺	2.65 (1.22, 5.74)	6.2-41.0
24 City ^f	SO ₄ ⁻	3.02 (1.28, 7.03)	18.1-67.3
24 City ^f	PM _{2.1}	1.97 (0.85, 4.51)	9.1-17.3
24 City ^f	PM ₁₀	3.29 (0.81, 13.62)	22.0-28.6
Southern California ^g	SO ₄ ⁻	1.39 (0.99, 1.92)	—
Decreased lung function in children			
Six City ^{d,h}	PM _{15/10}	NS Changes	20-59
Six City ^e	TSP	NS Changes	39-114
24 City ^{i,j}	H ⁺ (52 nmoles/m ³)	-3.45% (-4.87, -2.01) FVC	—
24 City ⁱ	PM _{2.1} (15 $\mu\text{g}/\text{m}^3$)	-3.21% (-4.98, -1.41) FVC	—
24 City ⁱ	SO ₄ ⁻ (7 $\mu\text{g}/\text{m}^3$)	-3.06% (-4.50, -1.60) FVC	—
24 City ⁱ	PM ₁₀ (17 $\mu\text{g}/\text{m}^3$)	-2.42% (-4.30, -0.51) FVC	—

^aEstimates calculated annual-average PM increments assume: a 100 $\mu\text{g}/\text{m}^3$ increase for TSP; a 50 $\mu\text{g}/\text{m}^3$ increase for PM₁₀ and PM₁₅; a 25 $\mu\text{g}/\text{m}^3$ increase for PM_{2.5}; and a 15 $\mu\text{g}/\text{m}^3$ increase for SO₄⁻, except where noted otherwise; a 100 nmole/m³ increase for H⁺.

^bDockery et al. (1993)

^cPope et al. (1995)

^dDockery et al. (1989)

^eWare et al. (1986)

^fDockery et al. (1996)

^gAbbey et al. (1995a,b,c)

^hNS Changes = No significant changes.

ⁱRaizenne et al. (1996)

^jPollutant data same as for Dockery et al. (1996)

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR BOXER

Question 1. As you may know, last Congress I introduced a bill entitled The Children's Environmental Protection Act. Among other things, my legislation would require EPA to set all health and safety standards at levels that protect our children and other sensitive subpopulations. Last September you announced that the Clinton Administration shared this goal and I am pleased that in announcing these proposed standards, and in your testimony, you indicated that these standards are intended to accomplish this goal.

Do you believe that you could make a decision to promulgate air quality standards equivalent to current standards which still meet the goals of protecting children and sensitive subpopulations?

Answer. Based on the record before the Agency at the time of proposal, including the advice and recommendations of the CASAC panels, the Administrator concluded—subject to further consideration based on public comments—that the proposed standards were requisite to protect the public health, including sensitive populations, with an adequate margin of safety. Given the at risk populations affected by these pollutants—children, asthmatics, the elderly—as well as possible effects on outdoor workers and other healthy adults, it was the Administrator's judgment that it was appropriate to propose standards that tended to fall in the lower end of the range of protection supported by my independent science advisors and recommended by experts in my technical offices.

Specifically, with regard to particulate matter, because of the consistency and coherence across the large number of epidemiological studies conducted in many different locations, the seriousness and magnitude of the health risks, and the fundamental differences between "fine" and "coarse" fraction particles, the CASAC scientists and the Agency clearly believed that "no action" was an inappropriate response to protect children, asthmatics, and the elderly.

With regard to ozone, the decision to propose the 0.08 ppm ozone standard with a 3rd-highest daily maximum 8-hour average (averaged over a 3-year period) was based upon the scientific information contained in the ozone Criteria Document, the analyses and staff recommendations in the ozone Staff Paper, and the scientific discussions and advice of the CASAC. The CASAC members unanimously recognized the need for replacing the current 1-hour standard with an 8-hour standard, and eight members offered personal views as to the appropriate level of an 8-hour standard. Of the four human health experts on the CASAC Panel, three favored a level of 0.08 ppm and the other favored a level of either 0.08 or 0.09 ppm. No Panel member favored a standard level of 0.07 ppm; three others favored 0.09 ppm, and one favored either 0.09 or 0.10 ppm combined with new public health advisories when O₃ concentrations are at or above 0.07 ppm.

In 1989, when the CASAC chairman wrote to the Administrator about the scientific basis for the current ozone primary standard, it was recognized that maintaining the 1-hour standard at 0.12 ppm would provide "little or no margin of safety." Since 1989, numerous new scientific investigations have demonstrated health effects associated with longer-term averaging times at levels as low as 0.08 ppm.

Weighing all of this information and the staff and CASAC recommendations in the context of the analyses conducted to assess the health risks to sensitive subpopulations, the EPA chose the proposed standard as providing better protection than an 8-hour standard of 0.09 ppm, which by some metrics would be approximately equivalent to the current 1-hour standard.

Question 2. Do you believe that the current research and data regarding the impact of air pollution on children understates the impact on children? Please explain.

Answer. Perhaps. Many of the health endpoints (e.g., lung inflammation, airway reactivity, childhood asthma) which have been reported in current human health studies have not been analyzed in terms of public health risk associated with exposure to ambient ozone levels. There are also numerous health endpoints (e.g., accelerated aging of lung tissue, lung scar tissue, increased susceptibility to respiratory infection) which have been observed in animal toxicology studies but have not yet been fully extrapolated to human health effects data due to differences in species sensitivity and dosimetry. For example, there is a lack of adequate information on the possibility that repeated airway inflammation in children could lead to later development of chronic respiratory disease and impaired development of lung tissue. All of these limitations could contribute to understating the impact of ambient ozone exposures on children.

Question 3. Some have suggested delaying one of the two standards. Aren't the strategies for compliance with the ozone and particulate matter standards similar?

Therefore, isn't it more economically efficient to promulgate the rules simultaneously?

Answer. In its proposal, EPA concluded that the effects and control of each are in many instances linked and will be affected by the other. For this reason, EPA stated in the proposal its intent to review and, as appropriate, modify both standards on a similar schedule. First, the same atmospheric chemical processes form both pollutants. Many of the atmospheric chemical reactions which form ozone are also responsible for production of PM_{2.5}. Second, many of the precursors for ozone and PM_{2.5} come from common sources. For example, nitrogen oxides from fossil fuel fired power plants are ozone precursors. These same power plants also emit sulfur dioxide which is a PM_{2.5} precursor. Control decisions affecting any power plant would be more efficient if they are made with a full appreciation of all the obligations the plant may be facing as opposed to a piecemeal approach. Finally, the Regional Haze Program will benefit from the joint implementation of the PM_{2.5} and ozone NAAQS because, again, many of the ozone and PM_{2.5} precursors are primary causes of visibility impairment.

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR
LAUTENBERG

Question 1. I understand that EPA estimates children will experience 1.5 to 2 million fewer incidents of significant decreases in lung under the new standards for ozone. Why are children affected by ozone more than adults, and is there any data that indicates whether these affected children experience any problems in later life as a result of decreased lung function in childhood?

Answer. Exposure analyses indicate that during the summertime when ozone levels are higher, children spend more time outdoors engaged in active behaviors which increase total ozone breathed and resulting health impacts. Because children often do not experience ozone-induced respiratory symptoms (e.g., cough, chest pain), which act as early warning signals, they may continue to play outdoors even when ambient ozone levels are higher and may cause adverse health effects. Although children will experience reductions in FEV₁ (reduced lung function) when exposed to higher ambient ozone concentrations, these effects tend to be transient and are not believed to cause problems later in life. However, health effects such as repeated lung inflammation, centriacinar lesions, and lung tissue damage may result in problems as children grow older. When repeated over a season or over many seasons, these effects may lead to irreversible damage and/or accelerated aging of the lungs, and may limit full development of lung tissue. Such effects have been observed in controlled-exposure animal toxicology studies but have not been confirmed to date in human health effects studies.

Question 2. One of the benefits of the tighter ozone standard which the Regulatory Impact Analysis didn't consider is the reduction of toxic air pollution. The Clean Air Act has led to a significant reduction in certain cancer-causing chemicals, known as Volatile Organic Compounds. For example, benzene has been reduced by 30 percent. Under your proposed new standard, do you agree that these types of carcinogens would be further reduced? Shouldn't that reduction have been included in the cost-benefit analysis performed as part of the Regulatory Impact Analysis?

Answer. Various benefit categories associated with the newly proposed ozone standard could not be monetized in the November 1996 Regulatory Impact Analysis (RIA). One example is the benefits associated with reductions of toxic air pollutants beyond those that occur as a result of existing requirements. Reductions in ambient ozone concentrations are achieved through reductions in emissions of volatile organic compounds (VOCs) and/or reductions in nitrogen oxides. In addition to contributing to ozone formation, some VOCs are carcinogens or can potentially cause a wide range of adverse health effects. In addition, the same types of chemical reactions in the atmosphere that create ozone can also create toxic air pollutants. The benefits associated with reduced cancer and other health impacts from air toxics, however, could not be monetized in the RIA because of data and time limitations.

Numerous other benefit categories, such as reduced nitrogen deposition in estuaries, reduced damage to urban ornamentals, reduced lung function effects, etc. could not be monetized in the November 1996 RIA. Also, the benefits of particulate matter reductions accruing from controls designed to reduce ozone concentrations could not be assessed. Work is underway to monetize and include additional ozone reduction benefit categories (including the benefits associated with reductions in some toxic air pollutants) in the revised RIA scheduled for completion July 1997.

Question 3. Opponents have claimed that CASAC advisors could not agree on the appropriate standards to recommend for clean air. But CASAC unanimously supported moving to an 8-hour standard for ozone and 19 of 21 members supported moving to a fine particle standard for particulates. In what areas were there any disagreements among CASAC members?

Answer. CASAC reached consensus that the Staff Papers for both ozone and PM provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning the two standards. With regard to ozone, the CASAC members unanimously agreed that the 1-hour primary ozone standard should be replaced with an 8-hour standard and that a secondary standard more stringent than the current standard was needed to protect vegetation. Furthermore, they agreed that the form of the primary standard should be changed from the current one-expected-exceedance form to one which allowed for multiple exceedances. There was a diversity of personal opinion on the appropriate level for the ozone primary standard. Of the four clinical human health experts on the panel, three supported a level of 0.08 ppm, and one supported a level of either 0.08 or 0.09 ppm. Of the other four panel members who offered personal views, three recommended that the level be set at 0.09 ppm and one member supported a range from 0.09 to 0.10 ppm but with public health advisories beginning at 0.07 ppm.

With regard to PM, there was a clear consensus on CASAC that a new PM_{2.5} standard should be established, with 19 of 21 members endorsing the concept of a 24 hour and/or an annual PM_{2.5} standard. There was less consensus on specific standard levels among members expressing personal opinions on the matter. Eight panel members supported staff recommendations for PM_{2.5} standards, but expressed no opinion on selecting specific levels. Of the 11 who offered opinions, 6 supported levels within the ranges recommended by EPA staff, with the other 5 supporting levels above that range. EPA proposed standards that are in the lower to middle part of the range recommended by those CASAC members who chose to express their opinions.

A majority of CASAC members recommended that, while adding the fine particle standard, EPA should keep the present PM₁₀ 24-hour standard at least as an option to be considered. EPA proposed keeping that standard, as well as an option that would eliminate it. Those CASAC panel members who commented on the issue recommended that EPA change the form of the PM₁₀ standard to one that is more "robust" or flexible than the current form; EPA proposed such a form.

There was also CASAC consensus on the staff's recommendations regarding the secondary effects of PM; i.e., that EPA not establish a separate national secondary standard for protecting visibility but pursue a separate regional haze program, and that there was an inadequate basis for establishing a secondary NAAQS to reduce soiling and material damage effects.

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR WYDEN

Question 1. After Congress passed the 1990 Clean Air Act, a number of areas in Oregon were designated non-attainment and the levels of particulate pollution in the Klamath Falls area were among the worst in the entire country. Today there is not a single area in Oregon that is not meeting air quality standards. As EPA goes forward with implementation of its proposals to change the current standards, will EPA give any special recognition to the areas—including those in Oregon—that have made progress in meeting the current standards? Will the areas that have made progress be given greater flexibility, for example, in implementing the new standards or will they (be) treated the same as other areas that made little or no progress in improving their air quality over the last 7 years?

Answer. EPA is aware of the accomplishments of Oregon nonattainment areas in meeting the PM₁₀ NAAQS. In fact, EPA publicly acknowledged the specific accomplishments of Klamath Falls in the Agency's National Air Quality Emissions Trends Report for 1991. While public recognition is important, under the Clean Air Act, the formal method for recognition of these accomplishments is to redesignate existing nonattainment areas to attainment. Consistent with Clean Air Act requirements, EPA is ready to work with Oregon to complete the formal process of recognizing these accomplishments by redesignating these areas to attainment once such a request is received.

With respect to the proposed PM_{2.5} standard, all areas of the country would be implementing this new standard for the first time. The Agency has proposed an Interim Implementation Policy to deal with current PM₁₀ nonattainment areas. Since the Agency is proposing to retain a PM₁₀ NAAQS, those areas which did not make progress under the current PM₁₀ NAAQS will still be obligated to attain the PM₁₀

NAAQS. At the same time, the Agency is concerned about implementation of the proposed standards for PM_{2.5} and ozone and has formed the Subcommittee for the Integrated Implementation of the Ozone and Particulate Matter NAAQS and the Regional Haze Program. This Subcommittee, which was formed under the Federal Advisory Committee Act, and has representation from the State of Oregon as well as other stakeholders, is charged with providing advice and recommendations to the Agency. The emphasis of this effort is the development of innovative control strategies to achieve maximum flexibility and cost-effectiveness in the attainment of the NAAQS and achievement of regional haze requirements. This should help all areas of the country attain the proposed PM_{2.5} NAAQS in the most cost effective and flexible manner possible.

Question 2. Shouldn't areas that have data to show that they're making progress in meeting the current air quality standards focus their resources on meeting the new standards—on actually improving the air quality—rather than having to expend resources completing the paperwork needed to get officially reclassified as in compliance with the 1990 standards? If an area has monitoring data to show it is complying with current standards, what can EPA do to maximize the use of scarce resources to meet the new standards the Agency is proposing, rather than spending time and money on what is essentially a paperwork exercise?

Answer. Actions being taken to achieve the current ozone and PM standards are steps in the right direction toward achieving any new standards and EPA will continue to push for States and local areas to make progress in cleaning their air under the current standards as they move forward to implementing new standards. We agree that time should not be wasted on unnecessary paperwork but rather on real environmental improvements. This is why the Subcommittee on Integrated Implementation was initiated to focus on how to streamline and simplify the implementation process and the transition to new standards to minimize the impact on all parties concerned. The Interim Implementation Policy proposed for public comment on December 13 is the first step in this process. As we move forward to finalize that policy, we will be trying to balance the need for ensuring continued progress and moving to implementing new standards. We will keep your specific concerns in mind as we finalize this policy.

Question 3. How does EPA propose to account for regional differences in background levels of PM_{2.5} when establishing the annual concentration level for this pollutant and in implementing the new standard for this pollutant?

Answer. In the review, EPA concluded that background concentrations vary from the Eastern to the Western U.S. ("Background" is defined in the Staff Paper as the distribution of PM concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of PM and precursor emissions of VOC, NO_x, and SO_x in North America. Background is thus distinguished from regional background, which refers to PM concentrations of both natural and anthropogenic sources which may be transported from one region to another.) Accordingly, EPA estimated ranges of annual average concentrations for natural background PM_{2.5} in the Eastern and Western U.S. of 2–5 µg/m³ and 1–4 µg/m³, respectively. (It is important to note that the data used to establish the high end of these ranges reflect the estimated effects of background and anthropogenic emissions from within North America and therefore provide estimates of the upper bounds.) The proposed PM_{2.5} annual standard of 15 µg/m³ is well above these estimated natural background levels.

With respect to implementation of the standard, background levels of PM_{2.5} are considered in the development of State Implementation Plans (SIPs) which are designed to produce attainment of the NAAQS. As a part of this planning process, States would explicitly include the background concentrations of PM_{2.5} in their area when designing control strategies. This level of background would affect the control strategies; e.g., as a general matter, in areas where the background is high, the control strategies are more stringent than in areas where the background is low. At the same time, if there are programs to reduce regional or national background levels, the States are allowed to account for this in designing control strategies. For example, the implementation of the Acid Deposition Program will reduce regional background concentrations of PM_{2.5}. Therefore, States are allowed to account for these changes in background when they develop their SIP control strategies; i.e., the overall effect of the implementation of the Acid Deposition program will be to reduce the stringency of State-developed control strategies for PM_{2.5}.

Question 4. You state in your testimony that one of the areas the new standards will likely focus on is emissions from power plants. As you know, there are currently efforts underway both in Congress and the States to restructure the electric power industry. These efforts could dramatically transform our nation's electric power sys-

tem. EPA is developing its implementation strategy over the next few months, without knowing how electricity restructuring may affect the industry in the future. How will EPA's implementation strategy for power plants provide flexibility to accommodate the changes that may occur in the electric power industry? Will you build in opportunities for periodic revisions of the strategy to reflect significant changes in the electric power industry and in other industries?

Answer. The EPA is very aware of current efforts to restructure our nation's electric power system. We are already performing sophisticated modeling efforts to assess the impact of restructuring on the industry and on air quality in the future. Results from these modeling efforts will assist us in designing our implementation strategy for attaining the newly proposed ozone and particulate matter national ambient air quality standards.

Over the next few years, the Agency will be developing an implementation strategy for attaining the new air quality standards. We have not yet finalized a strategy for achieving emission reductions from power plants. We are seriously exploring, however, a flexible market-based emissions trading strategy to achieve the NO_x and SO_x emission reductions (beyond those achieved via Title IV, the acid rain program of the Clean Air Act Amendments) needed to attain the proposed new standards. Such a strategy would provide maximum flexibility to achieve emission reductions at minimum costs and to accommodate changes that may occur in the electric power industry in the future. To the extent feasible, we will build in flexibility and opportunities for implementation program revisions should adjustments be required as a result of significant changes in the electric power industry.

Question 5. You state in your testimony that "sulphur dioxide reductions achieved by the acid rain program will greatly help reduce levels of fine particulates." Can greater use of emissions trading under the acid rain program also contribute to a reduction in fine particulate pollution and, if so, what will EPA do to increase emissions trading to help reduce particulate pollution?

Answer. Yes, particularly in the Eastern United States, additional sulphur dioxide emission reductions achieved through an emissions trading program can reduce ambient levels of fine particle concentrations significantly. The acid rain trading program has proven to be an extremely cost-effective strategy for achieving substantial SO_x emission reductions and for achieving subsequent fine particulate concentration reductions.

Primarily to reduce fine particle concentrations, EPA has been exploring options for expanding the acid rain SO_x trading program. In particular, through the Agency's Clean Air Power Initiative, EPA held a number of meetings with interested stakeholders to improve air pollution control efforts involving the power industry. Through these meetings, various options for expanding the acid rain trading program were developed.

EPA also has established a formal advisory committee under the Federal Advisory Committee Act to develop innovative, flexible, practical, and cost-effective implementation strategies to attain the new proposed ozone and particulate matter standards. Recently, the possibility of expanding the acid rain trading program to help attainment of the proposed particulate standard has been an issue of discussion among various interest groups represented within this committee.

Finally, the Agency is assessing the costs and benefits associated with expanding the acid rain trading program within an updated version of the Regulatory Impact Analysis (RIA) for the proposed particulate matter standard. The revised RIA will be completed July 1997.

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR INHOFE

Question 1. Ms. Browner, before the committee you stated that the PM studies showed a definite cause and effect. During the previous Science hearing the absence of a biological mechanism was verified by experts. In the CASAC closure letter dated June 13th, the panel stated:

"The diversity of opinion also reflects the many unanswered questions and uncertainties associated with establishing causality of the association between PM_{2.5} and mortality. * * *"

Is it your position that epidemiological studies, without a biological mechanism establish causality? What criteria does the Agency use in establishing causality? Since your finding of causality contradicts the scientific experts and the CASAC panel, what did you rely on for your findings?

Answer. As the Criteria Document points out, the interpretation of epidemiologic data as an aid to inferring causal relationships between presumed causal agents

and associated effects has long been addressed by several expert committees or deliberative bodies faced with evaluation of controversial biomedical issues (Page 12–3). Criteria for determining causality developed by these bodies are outlined in Chapter 12 of the Criteria Document. No single criterion is sufficient by itself, and it is not necessary that all criteria be fulfilled in order to support a determination of causality. While biological plausibility is one of the criteria, a full understanding of biological mechanisms is not. In her testimony as well as in the PM *Federal Register* Notice, the Administrator notes the distinction between having strong evidence of a cause/effect relationship and understanding how the relationship works at the level of biological mechanism. Numerous public policy judgments, from occupational guidelines and standards to the Surgeon General's 1964 decision on smoking, have been based primarily on epidemiological results, without an understanding of underlying biological mechanisms. In making such judgments, we cannot ignore epidemiological associations, especially when they provide consistent and coherent results across different cities, with different mixes of copollutants, and conducted by different researchers.

The Administrator bases her conclusions with respect to the likelihood of a causal relationship between air pollution containing particulate matter and health effects across a range of concentrations squarely on the comprehensive assessment of the evidence contained in the Criteria Document that was peer reviewed and approved for use in standard setting by her science advisors. It is important to note that the CASAC found that this Criteria Document reflected the "best ever example of a true integrative summary of the state of knowledge about the health effects and the various available indices of PM exposure" (Wolff, 1996).

With respect to the body of particulate matter epidemiologic data, both past and present criteria reviews leave little doubt about causality in regard to increased mortality and illness in relation to very high historic concentrations of particle-laden air pollutant mixtures (Criteria Document, pages 12–29), even though there is no accepted biological mechanism that explains these widely accepted conclusions. There is less consensus, however, with respect to how to interpret more recent studies, which suggest that these clearly demonstrated effects extend to concentrations well below those permitted by current air quality standards. The PM Federal Register Preamble summarizes the Criteria Document and Staff Paper assessments of a number of specific issues that have been raised regarding the adequacy and strength of the individual epidemiologic studies at 61 FR 65644–65648. The Criteria Document finds these studies have "clearly substantiated associations" of serious health effects with "exposures to ambient levels of PM found in contemporary U.S. urban air sheds even at concentrations below current U.S. PM standards." The Criteria Document evaluation of other possible explanations for the reported PM epidemiology results (e.g., effects of weather, other co-pollutants, choice of statistical models, exposure misclassification) finally concludes that "the reported associations of PM exposure and effects are valid."

Question 2. The relative risk factor for PM_{2.5} was established at or around 1.17. What other major rulemakings has the Agency undertaken with a relative risk factor in this range?

Answer. The relative risk of 1.17 referred to by the question appears in one of two long-term cohort studies and reflects the increase in risk of total mortality in populations living in the most polluted and least polluted cities studied. The corresponding relative risk for the most sensitive populations in these studies, those with cardiopulmonary diseases, is somewhat higher, in the range of 1.3 to 1.4. While relative risks of this magnitude are smaller than epidemiologists find in studies of occupational exposures and risks such as smoking, they are nevertheless quite significant from a public health perspective. Taken at face value, these long-term studies suggest that the lives of several tens of thousands of Americans may be shortened by up to 2 years or more. Even taking into account the recognized uncertainties associated with such estimates, these risk estimates rank particulate matter as one of the most significant public health issues EPA has ever addressed. Moreover, unlike some estimates of environmental risk, these estimates are based directly on epidemiological data on human mortality, not on an *extrapolation* from high-dose laboratory animal data.

Question 3. The committee has heard conflicting figures describing the number of PM_{2.5} studies, from hundreds, to 65, to 6. In an EPA reply to my written request for a list of all studies which examined PM_{2.5}, I received a list of 28 studies. Of these 7 were found not to be statistically significant, 4 found no association, and only six found significant association. If this is the case would you please provide a breakdown and explanation for the remaining studies the EPA has characterized as supporting the proposed regulations. How many other studies are there? What aspect

of PM_{2.5} did they study? If they did not examine PM_{2.5}, how are they relevant to this process? How many of these studies “found significant association” and how many were deemed “not to be statistically significant” or “found no association?”

Answer. The tabulation of record for studies considered by EPA is the Criteria Document and Staff Paper. There are literally thousands of studies on PM-related health effects, animal toxicology, controlled human studies, visibility impairment, soiling and nuisance, atmospheric chemistry and related topics referenced in the Criteria Document. In considering the question of which studies of particulate matter were of most significance to determining the potential health effects of particles at concentrations that extend to below those allowed by the current standards, EPA relied principally on the significant body of mostly recent community epidemiologic studies. As noted in the Preamble, of the more than 80 such PM studies that evaluated short-term concentrations of particulate matter and health that are summarized in Tables 12-2 and 12-8 to 12-13 of the Criteria Document (65 FR 65646), more than 60 reported positive, statistically significant associations. Tables 12-16, 12-21, and 12-22 summarize an additional 11 studies of long-term PM concentrations and health. Nine of these studies reported one or more statistically significant associations between particulate matter and health indicators. As discussed in the preamble and in the response to question 1 above, these long- and short-term studies were examined both individually and collectively in addressing the consistency and coherence of the evidence, ultimately supporting the Criteria Document conclusion that PM effects associations are real and suggesting a likely causal relationship. They are, therefore, directly relevant to the process, although in a more qualitative fashion.

These studies used a variety of indicators of particulate matter, including PM₁₀, PM_{2.5}, Total Suspended Particles (TSP), sulfates, hydrogen ion, British Smoke, and more. All of these indicators either contain or are themselves constituents of fine particles. Not all of these indicators are, however, readily useable for making the best quantitative estimates of risk. Therefore, the Criteria Document identified a more limited subset of these studies as most useful for making quantitative estimates of effects associated with thoracic particles (<10 um) and fine particles. This refined list of studies and related effects estimates are provided in Chapter 13 of the Criteria Document in Tables 13-3 to 13-5 (attached).

Your earlier request to Mary Nichols focused on studies that actually measured PM_{2.5} and fine particle components. Because neither the Criteria Document nor the Staff Paper listed in one place all studies using fine particle indicators, EPA staff prepared a separate summary drawn from these documents in response to discussions with your staff. This summary was provided to your staff on February 11 and to you in the February 1997 letter from Mary Nichols. In examining this summary, however, we found a somewhat different breakdown than that stated in your question:

- “The total number of studies in the summary was 32, of which 23 were short-term and 9 long-term;”
- Twenty-one studies had one or more significant associations between fine particle indicators and health endpoints;
- Seven studies found a positive result that was either not significant or could not be clearly distinguished; and
- Four studies found no association.

In response to your original question about which of these studies were most directly useful in establishing the proposed annual PM_{2.5} standard, six studies were highlighted in the summary provided. None of these studies relied on British Smoke or other optical indicators; these less certain indicators were not used for quantitative purposes for this proposal, even though such studies did form the principal basis for the current PM₁₀ standards. Only studies that actually measured fine particle mass were relied on directly for deciding upon the precise level to propose. All six of these studies showed a statistically significant association between fine particle mass and effects. Five measured PM_{2.5}, and one measured PM_{2.1}. The five studies directly measuring PM_{2.5} are the same ones included on the Chart used by the Administrator in her recent Senate testimony. Air quality information from other PM_{2.5} studies noted in the summary provided supplemental support in deciding on what levels to propose for the PM_{2.5} standards.

Question 4. During the Science Hearing Dr. Schwartz stated:

“I am relatively convinced that the particles larger than 2.5 microns are not important for most of the health effects. It is really the combustion particles that matter. Combustion particles are less than 2.5 microns, but mostly they are less than 1 micron in size. Ultra fine particles come right off the combustion process. You get these very, very small particles and

then they agglomerate up and tend to get bigger. They tend to grow up to things that are around .3 microns, roughly.”

Has the Agency ruled out the ultra fine particles as a health risk? Is it possible they are a more significant threat than PM_{2.5}?

Answer. “Combustion particles” include directly emitted “ultrafine” (<0.1 μm) particles that quickly aggregate into larger sizes as well as particles that form in the air from reaction of gases such as sulfur dioxide. Both the Criteria Document and the Staff Paper examine the potential contribution of directly emitted ultrafine particles to the observed effects of particulate matter. The Criteria Document points out that such ultrafine aerosols (<0.1 μm) are a class of fine particles that have the potential to cause toxic injury to the respiratory tract as seen in several animal studies (p. 13–76). The Staff Paper assessment includes the following evaluation of potential risk:

“Because of their short lifetime, it is unclear that unaggregated ultrafine particles make up any significant fraction of the mass of fine particles or of PM₁₀, other than in the vicinity of significant sources of ultrafine particles. The relationship between ultrafine numbers (or mass) and the mass of fine or thoracic [PM₁₀] particles found in typical community air pollution has not been established. Although the Criteria Document provides little direct information, it might be expected that penetration and persistence of unaggregated ultrafine particles to indoor environments would be limited. For these reasons, it is questionable whether ultrafine aerosols could be playing a major role in the reported epidemiologic associations between the measured mass of fine or PM₁₀ particles and health effects in sensitive populations” (Staff Paper, p. V–72–73).

In summary, given their much longer atmospheric lifetime and broader dispersion from source regions, the larger fine particles appear to be of greater risk to public health. Because of the potential toxicity of ultrafine particles and the opportunity for exposure near combustion sources, however, they represent an area where additional research is necessary. In any event, strategies that control fine particles will focus new attention on both directly emitted and atmospherically formed ultrafine particles.

Question 5. Who will determine the implementation steps for these regulations? Based on past experience, what percentage would be determined by the States and local governments, and what would be mandated by the EPA in order to bring a nonattainment area into compliance? To what extent would States have flexibility to regulate implementation procedures? Will the Agency deem any particular procedure as mandatory, or to the contrary will the Agency prohibit a specific implementation procedure, such as barbecuing?

Answer. Under the Clean Air Act, EPA has responsibility to set the national ambient air quality standards (NAAQS). After the NAAQS are established, the Clean Air Act outlines the process and requirements for the development of State Implementation Plans (SIPs). The States take the primary role in developing SIPs in accordance with the process and substantive requirements of the Act. The purpose of the SIP is to outline the specific emission reduction measures a State will implement to bring about attainment and maintenance of the NAAQS. In order to facilitate the development of approvable SIPs, EPA provides the States and local governments with the necessary technical tools and implementation guidance.

In developing SIPs, the States and local governments, within the constraints of the Clean Air Act, have the responsibility and flexibility to make specific choices as to which sources or source categories to regulate or not regulate. In some cases, the Act specifies more specific control programs such as Reasonably Available Control Technology (RACT) and New Source Review (NSR). The Act may also specify more general requirements for reasonable further progress or an attainment demonstration. EPA has historically not interpreted these more general control requirements to mandate specific control measures. EPA’s role is to review and approve or disapprove SIPs based on the requirements of the Clean Air Act. Finally, under the Clean Air Act, EPA has a duty to develop and implement certain national emission control programs, such as those for motor vehicles and acid deposition. While these actions contribute to attainment of the NAAQS and may have been adopted (in whole or in part) to facilitate attainment, they are not specifically intended to bring about attainment of the NAAQS.

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR ALLARD

Question 1. Ms. Browner, I would like to ask you to respond to a quote from last week's hearing. The quote is, "* * *" in a paper Lipfert and Wyzga published in the *Journal of the Air and Waste Management Association*, we examined many published studies that had looked at the relationship between daily mortality and various pollutants. We found that if a study had chosen to focus upon sulfur dioxide or nitrogen dioxide instead of particulate matter, that study found similar effects on daily mortality as did those studies that focused on particulate matter. A focus upon carbon monoxide indicated somewhat larger effects than particulate matter, and a focus on ozone gave somewhat smaller effects." If in fact this is true, how can we be certain the regulations you have proposed will protect human health when in fact you may have identified the wrong pollutant? How do we know that we won't mandate the expenditure of billions of dollars only to have identified the wrong cause of mortality?

Answer. The conclusions reflected in the quote are not wholly supported by the Lipfert and Wyzga (1995) paper referenced. For example, in comparing their measure of risk among pollutants, the authors base their conclusions on 41 instances showing associations between measures of particulate matter and mortality, but found only 3 such cases for carbon monoxide. This is hardly a basis for any conclusion about the relative size of carbon monoxide effects. In fact, the "larger" value referred to for carbon monoxide is driven by a single study in Sao Paulo, Brazil. In that study, when PM and carbon monoxide are entered together into the analyses simultaneously with other pollutants, the PM risk measure (elasticity) is stable, while that for carbon monoxide drops by more than a factor of 5, and is only $\frac{1}{4}$ that for PM. As Lipfert and Wyzga (1995) state in their paper "In examining the joint regressions, we noted instances where SO₂, CO, and O₃ contributions were less in the joint regressions than in separate regressions."

The issue highlighted here, that of the potential effects of co-pollutants is, nevertheless, an important one. Because different air pollutants are often correlated with each other over time, and multiple air pollutants may contribute individually or collectively to health effects, it is important to examine particulate matter effects studies to assess the potential for what is termed "confounding" and "effects modification" by co-occurring pollutants. The Lipfert and Wyzga (1995) paper is a limited review of the literature, that was fully evaluated in EPA's and CASAC's scientific review and cited in the Criteria Document, the Staff Paper, and the PM *Federal Register* Notice. Unlike this single paper, the Criteria Document contains a comprehensive, thorough, and more recent review of the PM health effects literature, particularly with respect to the specific issue of the effects of co-pollutants. The treatment of multiple pollutants in individual studies is dealt with most cogently on pages 12-329 to 12-344 of the Criteria Document. The findings as summarized in the integrative synthesis of PM effects are as follows:

"Confounding by co-pollutants sometimes cannot be avoided. In studies where sensitivity analyses demonstrate that including other pollutants in the model cause little change in either the RR [relative risk] estimate for PM or the width of the confidence interval for the PM effect, one may conclude that the model is not seriously confounded by co-pollutants. Some studies of PM related mortality or morbidity have shown the specific relative risk estimates for PM only in the respective models to be little changed by inclusion of other co-pollutants in the model, suggesting little confounding in those cases. On the other hand, in those analyses where the RR estimate for PM was notably diminished by inclusion of other co-pollutants in the model (indicative of some confounding), the PM effect typically still remains statistically significant, although reduced. Since a number of mortality and morbidity studies have shown that the PM effect on health is not sensitive to other pollutants, we may conclude that findings regarding the PM effects are valid" (Criteria Document, p 13-57).

As noted in the Criteria Document, it is reasonable to expect that co-pollutants present in some study areas might modify (either increase or decrease) the apparent effects of PM by atmospheric interactions or by interactive effects on sensitive subpopulations. Moreover, the possibility of exposure misclassification for gaseous pollutants such as carbon monoxide or sulfur dioxide could modify their apparent significance relative to PM. Another way to examine this issue is to compare study results from multiple areas with varying degrees of co-pollutant concentrations. If such PM confounding or effects modification was occurring to an appreciable degree, the associations with PM would be expected to be consistently high in areas with high co-pollutant concentrations, and consistently low in areas with low co-pollutant concentrations. However, EPA's examination of reported PM₁₀-mortality associa-

tions as a function of the varying levels of co-pollutants in study areas found that consistent effects estimates were observed across wide ranges of co-pollutant concentrations (Staff Paper, Figures V-3a, V-3b). In essence, the PM effects estimates were similar in vastly different geographic locations with high and low concentrations of pollutants such as sulfur dioxide, nitrogen dioxide, ozone, and carbon monoxide and varying climactic conditions. This consistency and coherence of the PM health effects data further support a significant contribution of PM, alone or in combination with other pollutants, to the observed increases in mortality and morbidity (Criteria Document, page 13-1).

Based on the most comprehensive assessment of available scientific evidence, the Administrator believes that her proposal, in combination with existing standards and programs, will result in regulating the correct pollutants, and that strategies that reduce fine particulate matter will materially reduce the risk of adverse health effects.

Question 2. Are you arguing that there is a completely accurate relationship between PM people breathe with the levels used in air pollution health studies?

Answer. The PM to which people are exposed is composed of particles from outdoor sources (e.g., industrial sources, cars, diesel engines) and indoor sources (e.g., cigarette smoke, cooking). The exposure to particles of outdoor origin is the part of exposure that is relevant to the national *ambient* air quality standards.

As noted in the preamble to the proposal (61 FR 65645) one difficulty in interpreting the epidemiological studies, particularly for quantitative purposes, is the uncertainty and possible bias introduced by the use of outdoor monitors to estimate a population-level index of exposure.

The Staff Paper and Criteria Document conclude that central ambient monitoring can be a useful, if imprecise, index for representing the average exposure of people in a community to PM of outdoor origin. In addition, the documents conclude that measurements of daily variations of ambient PM concentration have a plausible linkage to the daily variations of human exposures to PM from ambient sources for the populations represented by the ambient monitoring stations. Furthermore, this linkage will be better for indicators of fine particles than for indicators of fine plus coarse particles (i.e., PM₁₀ or TSP). Thus, it is reasonable to use a representative central ambient monitor or spatially averaged group of monitors to represent the mean community exposure to particles from outdoor sources.

Question 3. Would you concede that the science in this area is not as well developed as it should be (Phillipsburg and Azusa, monitored v. personal exposure)? If not would you concede that there is a difference of opinion in the mainstream scientific community?

Answer. Both the Staff Paper and the proposal preamble point out that a comprehensive treatment of the potential influences of exposure misclassification and measurement error is an important research need. The uncertainties regarding human exposure do not invalidate the associations reported in the literature. The available evidence on the consistency of the PM effects relationships in multiple urban locations with widely varying indoor/outdoor conditions and a variety of monitoring approaches makes it less likely that the observed findings are an artifact of errors in measurement of pollution or of exposure.

Furthermore, in a supplemental letter (Lippmann et al., 1996), four of the CASAC health scientists stated:

* * * although population exposure to air pollution cannot be perfectly estimated based on central monitoring, these inherent errors in exposure estimation are more likely to cause an underestimation of the adverse health effects associated with pollution exposure, particularly in longitudinal [day-to-day] cohort studies where individual risk factors and exposures are directly related to health effects. Thus the consistent positive findings cannot be attributed to exposure measurement error. Furthermore, there is growing evidence that fine particles are more uniformly distributed over large geographic areas than are coarse particles ([Criteria Document,] Section 13.2.4), that measurements at one site give a reasonable estimate of the fine particulate concentrations across a city ([Criteria Document,] Section 13.2.6), and that fine particles penetrate and have longer lifetimes indoors than coarse particles ([Criteria Document,] Section 13.2.6). This evidence supports using ambient measures of fine particles at a central site as an acceptable estimate of the average exposure of people in the community ([Criteria Document,] Section 13.2.6). For those reasons, we judge that uncertainties arising from air monitoring and human exposure estimation

do not negate the consistent excess mortality and morbidity associations.

* * *

Question 4. As you know the Denver Metro Area has not had an ozone violation since 1987. About 1 year ago Denver submitted an Ozone Maintenance plan to have them redesignated as an ozone attainment area. Obviously, we would like to have Denver in attainment with the old standards before any new standards come out. Further, since the *Federal Register* notice does not give an implementation date we would like to know that EPA will put Denver in attainment before these regulations go into place, will you talk to Region VIII about this?

Answer. EPA places a high priority on redesignation requests to attainment and is working diligently to redesignate Denver to attainment for ozone before a final decision on the new ozone NAAQS.

Although the Colorado Air Quality Commission took action on the maintenance plan nearly a year ago, Colorado law requires that all such rules undergo a legislative review before being forwarded by the Governor to EPA. Therefore, the redesignation package was not received by EPA until late summer 1996. Upon EPA's receiving the package and reviewing it, we discovered that it did not include a complete technical support document to justify the redesignation. We have not yet received the complete information from the State, but we are proceeding to review the package before us, awaiting the additional information. Hopefully, this delay will not adversely affect approvability before the final decision is made on the ozone NAAQS.

In the meantime, EPA will do everything possible to expedite the review.

Question 5. Finally, on an issue completely unrelated to this hearing, but important none the less, is the issue of State Self Audits. As you know Colorado has a self-audit law and I believe the state is being sued by an environmental organization over that law. I understand they [are] pressuring EPA to also oppose this form of state law. Does EPA have a position on this issue? If you are not prepared to answer here I understand but please reply in writing.

Answer. The EPA issued its final audit policy, "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations," on December 22, 1995. The policy encourages self-policing violations discovered through environmental audits or compliance management programs. The policy protects the public's right to know the nature of the problems disclosed by regulated entities under the policy, and it preserves the Agency's ability to recover any significant economic benefit gained by the violator. As of January 1997, 105 companies had disclosed violations at more than 350 facilities under the policy, proving that environmental auditing can be encouraged without blanket amnesties or audit privileges.

The EPA has worked with states in their efforts to craft policies and laws that offer incentives for environmental auditing but that do not impair state enforcement authority under delegated programs. Federal laws and regulations establish clear standards that states must meet to obtain approval to administer Federal environmental programs. The Agency supports state audit laws that neither impair the minimum requirements for adequate enforcement authority nor create evidentiary privileges that limit access to evidence of civil violations or criminal misconduct. Nevertheless, the Agency questions state audit immunity/privilege laws that place restrictions on the state's ability to obtain penalties and injunctive relief for violations of Federal program requirements, or obtain information that may be needed to determine compliance status. In analyzing the impact of such state audit laws, the EPA stands ready to consult with state officials to ensure the adequacy of enforcement authority in delegated state programs. In working with the states, the EPA relies on a policy document issued February 14, 1997, "Statement of Principles, Effect of State Audit Immunity/Privilege Laws on Enforcement Authority for State Programs," which articulates the minimum requirements for adequate enforcement and information gathering authority for the purpose of approving or delegating programs in states with audit privilege or immunity laws.

EPA Region 8 is currently analyzing the petition to revoke Colorado's authority to administer the Clean Water Act and will coordinate a response with EPA Headquarters. The petition was filed January 29, 1997, by a coalition of public interest groups, including the Sierra Club, the Western Colorado Congress, the Oil Chemical and Atomic Workers Union, and the High Country Citizens Alliance. The petitioners claim that the Colorado audit privilege and immunity law has impaired the state's ability to adequately enforce the NPDES program and has eliminated sufficient opportunities for public participation. In assessing the petition, the EPA will consider the factors outlined in the Statement of Principles. EPA may consult the Colorado Attorney General or other state officials if clarification is needed as to the effect of the audit law.

RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR REID

Question 1. Given that we all agree that overall air quality has been improving in the U.S. in recent years, it has been argued to me that EPA is moving the goal post on this issue. Much of the Nation is not currently in attainment of either the current ozone standard, the existing PM₁₀ standard or both. Might it not be a better use of the nation's resources to focus on attaining the current standards before we tighten them?

Answer. We also are proud of the accomplishments to date under the Clean Air Act in improving air quality in the U.S. EPA is not "moving the goal post" but rather is attempting to maintain the goal of the CAA since its original enactment in 1970: setting national ambient air quality standards which protect public health with an adequate margin of safety and protect public welfare from known or anticipated adverse effects. Based on the recent review of the science and consistent with the recommendations of the CASAC, the Administrator has concluded, subject to public review and comment, that the current standards for PM₁₀ and ozone do not meet the goal of the CAA and therefore has proposed revised standards for ozone and PM₁₀ and new standards for PM_{2.5}.

While we share your concern about the cost of achieving these standards, it is important to note that EPA's recent draft study of the costs and benefits of the Clean Air Act found billions of dollars of benefits from implementing the former Total Suspended Particulate Matter (TSP) standards. Our concern about the costs has led us to work with States, environmental groups, industry, small business representatives, and academia through our FACA Committee to develop more flexible, cost-effective strategies for achieving these standards. We believe, as has been demonstrated in the past, that the public health can be protected at lower costs than are anticipated either at the time of setting a standard or passage of environmental legislation.

Question 2. Local and state air quality control personnel have expressed concerns to me about the cost of implementing these regulations, and particularly of developing a PM_{2.5} monitoring network. Although this is an implementation issue, how does EPA intend to distribute the financial burden of implementing the standards and developing the required monitoring network?

Answer. It is currently estimated that EPA's proposed monitoring regulations for PM_{2.5} will cost \$70.8 million for 1200 stations. EPA will provide 60 percent of this burden through the Federal 105 Grant funds, with the other 40 percent of the costs provided by State and local agencies. The Federal share will be provided by a combination of new and reprogrammed funding requested in the fiscal year 1998 budget. Within existing monitoring programs, we plan to shift emphasis away from certain criteria pollutants (for which we have successfully reduced ambient levels) and toward PM_{2.5} monitoring. Examples include a reduction of monitoring sites for sulfur dioxide, lead, carbon monoxide and nitrogen dioxide, as well as PM₁₀. While EPA is shifting resources and requesting new funding for PM_{2.5}, we foresee the States proportionally sharing the costs of developing the PM_{2.5} monitoring network.

The initial samplers would be allocated to provide geographic coverage with added initial emphasis on high population, high potential PM_{2.5} pollution areas and high ozone areas. All new samplers will include both Federal Reference Method monitors, special purpose monitors and continuous PM analyzers. In addition, special monitoring studies are needed with emphasis on designing adequate networks to lay the ground work for future strategy development. Because we are proposing to maintain PM₁₀ standards, with modest revisions, we project gradual offsets from the current PM₁₀ monitoring program. We are currently developing interim PM program guidance which continues much of the PM₁₀ program while transitioning to the PM_{2.5} program.

The table below outlines the current strategy for phasing in the PM_{2.5} monitors and phasing-out of some of the PM₁₀ monitors. The table identifies the number of PM₁₀ and PM_{2.5} sites and the estimated total cost of the PM₁₀ and PM_{2.5} program.

	Approximate No. of Operational Sites			Estimated National PM Cost [In millions of dollars]		
	Year	PM ₁₀	PM _{2.5} *	PM ₁₀	PM _{2.5}	Total
0	1997	1600	200	15.9	4.2	20.1
1	1998	1400	600	12.6	18.6	29.9
2	1999	1000	1000	9.8	24.0	33.8
3	2000	600	1200	6.7	24.0	30.7

*Totals include approximate number of sites operating at the end of the year.

Question 3. Realizing that costs cannot be considered in modifying the national ambient air quality standards. However, the initial analysis the Agency has done on changing the ozone standard seems to indicate that costs outstrip benefits by a comfortable margin. Again, realizing that there are only so many resources that can be aimed at these problems, is the ozone control program really the one that will give us the greatest environmental “bang for the buck”?

Answer. The Clean Air Act requires EPA to set standards that protect the public health with an adequate margin of safety and protect the public welfare from known or anticipated adverse effects without consideration of costs. For 26 years, the Clean Air Act has promised American adults and American children that they will be protected from the harmful effects of dirty air. EPA believes that the public has a right to know if the air quality in their area is unhealthy on a particular day. This information allows them to take personal actions to protect their health or the health of their family if they are at risk.

Concerning the costs and benefits associated with achieving the proposed ozone standard, it is important to note that those estimates reflect only the monetized costs and benefits. There are many benefits likely to be associated with the standard that we are not able to monetize such as reduction of the following endpoints: chronic respiratory damage, premature aging of lungs, susceptibility to respiratory infection/impairment of respiratory tract defense mechanisms, cancer and other health effects caused by toxic pollutants (ozone and PM controls will reduce toxics), alteration of airway responsiveness, incidence of significant changes in pulmonary function, reduced acute inflammation and respiratory cell damage, nitrogen deposition in sensitive estuaries (like Chesapeake Bay), impacts on national parks, non-commercial forests, and ecosystems, impacts on growth and survivability of tree seedlings, materials damage (e.g., dirt on buildings), mortality/morbidity from lower fine particle levels from ozone controls, visibility impairment resulting from ozone controls, and damage to urban ornamentals (e.g., grass, flowers, trees, shrubs) from ozone controls. Despite the existence of all of these currently non-monetized benefit categories, the partial attainment monetized benefit estimates presented in the Agency’s Regulatory Impact Analysis ranged as high as the lower bound of associated costs.

We formed the FACA Subcommittee for the Integrated Implementation of the Ozone and Particulate Matter NAAQS and the Regional Haze Program to look at ways to achieve all of these standards in the most cost-effective manner. Nitrogen oxides and organic compounds can contribute to all three types of air quality problems and by looking for opportunities of multiple benefits from controlling different sources of these pollutants, the air quality problems can be addressed more efficiently. In addition, the Subcommittee is also investigating how market-based strategies can be used to further reduce the cost of achieving the standards.

Question 4. Again, skipping ahead to implementation. I have been very impressed with the recent success of several air programs that promote regional solutions, flexibility and market mechanisms to promote more cost-effective compliance. The Acid Rain Program, in particular, comes to mind. Do you anticipate an implementation plan for the new ozone and PM_{2.5} standards that will encourage such flexibility?

Answer. Yes. In fact, EPA expects that the continued implementation of the Acid Rain Program will play a major role in the attainment of the PM_{2.5} NAAQS. In addition to this, in September, 1995, EPA formed the Subcommittee for the Integrated Implementation of the Ozone and Particulate Matter NAAQS and the Regional Haze program under the Federal Advisory Committee Act. This Subcommittee was charged with the goal of developing innovative control strategies that integrate ozone, PM and regional haze considerations. The ultimate goal of this effort is to produce approaches which achieve maximum flexibility and cost effectiveness in the attainment of the NAAQS and in achievement of regional haze requirements. The Subcommittee is actively exploring a number of flexible approaches based on regional solutions and market mechanisms. This includes the use of economic incentives and broad-based market trading mechanisms to bring about attainment of the NAAQS and achievement of regional haze requirements.

Question 5. You are planning to spend \$18 [million] this year for PM_{2.5} research and the budget request suggests that you plan to spend \$24 million in next year. Please explain how any findings unearthed by this research will impact the implementation of these regulations.

Answer. It will take several years to put an implementation program in place for the new standards. The effort to conduct monitoring and develop control programs will reveal additional scientific and technical information needs. The research done over the next few years, including that conducted through this and next years budgets, could be of significant benefit in improving these ongoing programs, as well as

improving the quality of the next criteria and standards review. One category of our fiscal year 1997 and 1998 research is directed toward producing data and tools useful in guiding implementation strategies. This component of the research includes:

- determining source contributions to ambient PM concentrations and the availability, performance, and cost of risk management options to meet ambient PM standards;
- understanding the atmospheric chemistry of PM to support fate and transport modeling used in implementation; and “development and evaluation of improved particle measurement methods to characterize atmospheric PM.
- The other major component of the research program will focus on health effects, including potential mechanisms, population exposures, and advances in community studies. This information will support the next review of the standards, which will occur before final implementation plans are due.

Question 6. In recent years, EPA’s efforts on particulate matter have focused on smaller and smaller particles, which has led to the current call for a PM_{2.5} standard. All of this seems to suggest that the Agency no longer believes that PM₁₀ is the threat it once was. Why not just repeal the standard?

Answer. While EPA recommendations for general particle standards have progressed toward smaller size particle standards, the most current review by EPA and CASAC make it quite clear that the 1987 establishment of PM₁₀ as an indicator for particulate matter was a wise decision. As noted in the preamble, “The recent information on human particle dosimetry contained in the Criteria Document provides no basis for changing 10 μm as the appropriate cut point for particles capable of penetrating to the thoracic regions (61 FR 65654).” More specifically, the CASAC advised the Administrator that “there is a consensus that retaining an annual PM₁₀ NAAQS * * * is reasonable at this time” (Wolff, 1996). While EPA believes there is strong scientific evidence suggesting that new fine particle standards should be established, there is also a clear need to retain PM₁₀ standards, at or near the level established in 1987, to provide complete protection of public health against all particle fractions of concern to public health.

Question 7. There has been some confusion about the health effects of ozone. Does ozone cause asthma? Or does it just make it worse for those who already have it?

Answer. Ozone has been shown to aggravate the symptoms and underlying physiological responses (e.g., lung inflammation) which are associated with asthma. Epidemiological studies have reported an association between ambient ozone concentrations and hospital admissions/emergency room visits for respiratory causes. Clinical research has provided evidence of greater reductions in lung function for asthmatics than for healthy individuals. Increased airway reactivity has been demonstrated in both healthy and asthmatic individuals following exposure to ozone. And, ozone exposures of human subjects have been reported to increase indicators of pulmonary inflammation, which could precede development or worsening of an asthma event. Thus, taken as a whole, research supports the contention that while ozone has not been seen to cause asthma, it contributes to health effects which worsen asthma.

Question 8. As you know, the Intermodal Surface Transportation Efficiency Act is up for reauthorization this year. With the possibility of so many additional communities falling into non-attainment, has EPA had any interaction with the Department of Transportation about issues of attainment, conformity, and the allocation of resources under ISTEA? If yes, please describe.

Answer. Yes. While developing the Administration’s proposal, the Department of Transportation (DOT) consulted with EPA on issues pertaining to how the proposed standards would be addressed in the Congestion Mitigation and Air Quality Improvement Program (CMAQ). In the Administration’s proposal, newly designated areas that might result from the proposed standards would be eligible for funds under CMAQ after those areas had made a SIP submittal to EPA. These areas would be included in the apportionment formula for calculating CMAQ.

Question 9. Please provide copies of the large easel charts used by the Administrator at the hearing.

Answer. Copies of the large easel charts used by the Administrator are attached. [Attachments for the Record to Question 9 follow:]

Soot/Particulate Matter The Science Calls For Action

- "It was the consensus of the Panel that although our understanding of the effects of PM is far from complete, the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards."
- "There was also a consensus that a new $PM_{2.5}$ NAAQS be established, with nineteen [of 21] Panel members endorsing the concept of a 24-hour and/or an annual $PM_{2.5}$ NAAQS."
- Individual Panel members endorsed levels within the ranges of:
 $PM_{2.5}$ - 15-30 $\mu\text{g}/\text{m}^3$ Annual Average
20- \geq 75 $\mu\text{g}/\text{m}^3$ 24-Hour

Source: Clean Air Scientific Advisory Committee (CASAC) Closure on Staff Paper for Particulate Matter;
June 13, 1996



SMOG/OZONE

The Science Calls for Action

CURRENT STANDARD	PROPOSED STANDARD	
.12 ppm, 1-hour or .09 ppm, 8-hour	.08 ppm, 8-hour	
20 million	CHILDREN PROTECTED	33 million
4 million	ASTHMATICS PROTECTED	7 million
5 million	PEOPLE WITH RESPIRATORY DISEASES PROTECTED	8 million
74 million	TOTAL AMERICANS PROTECTED	122 million



Soot/Particulate Matter The Science Calls For Action

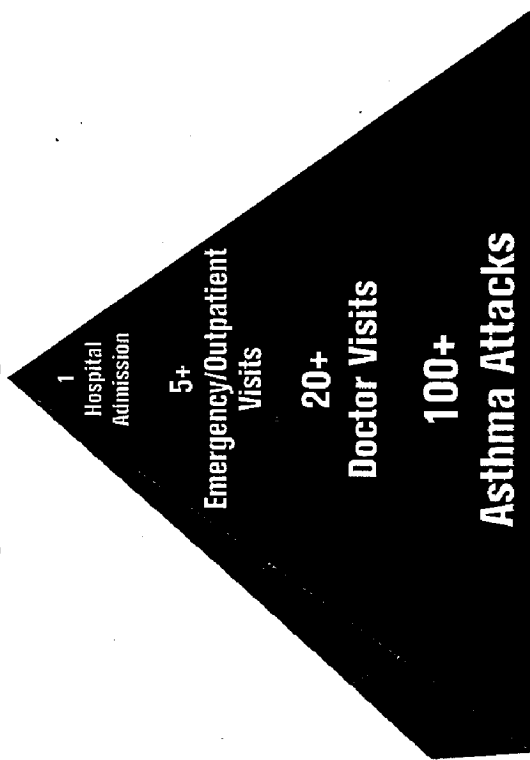
Compared to the current standards:

- 20,000 fewer premature deaths
- 250,000 fewer cases of aggravated asthma
- 250,000 fewer incidences of acute childhood respiratory problems
- 60,000 fewer cases of bronchitis
- 9,000 fewer hospital admissions



Hospital Admissions are the Tip of the Iceberg

For Every 1 Hospital Admission:



Cite: U.S. Department of Health and Human Services (1994) National Hospital Ambulatory Medical Care Survey: 1992 Summary.
The New York Electricity Externality Study (1995) Rowe et al.

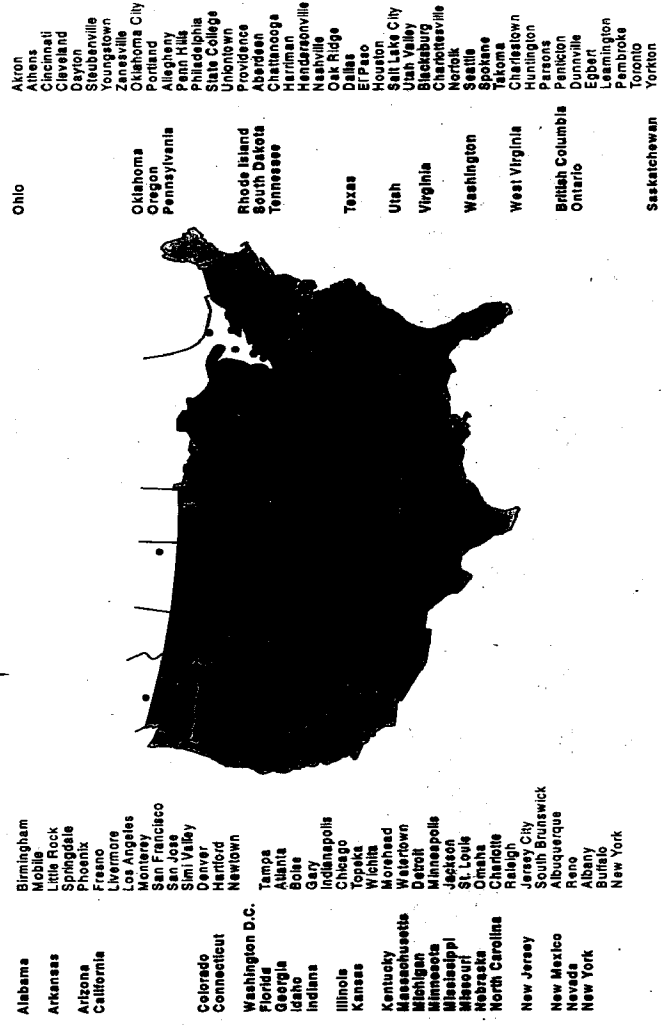


Soot/Particulate Matter The Science Calls For Action

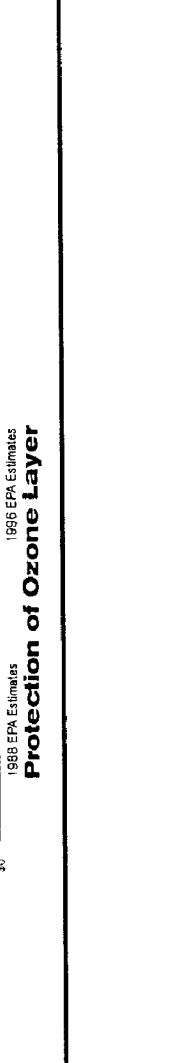
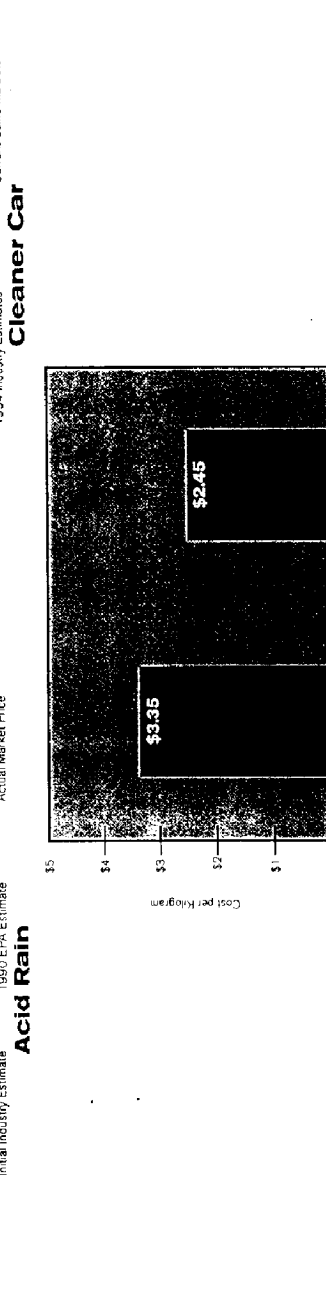
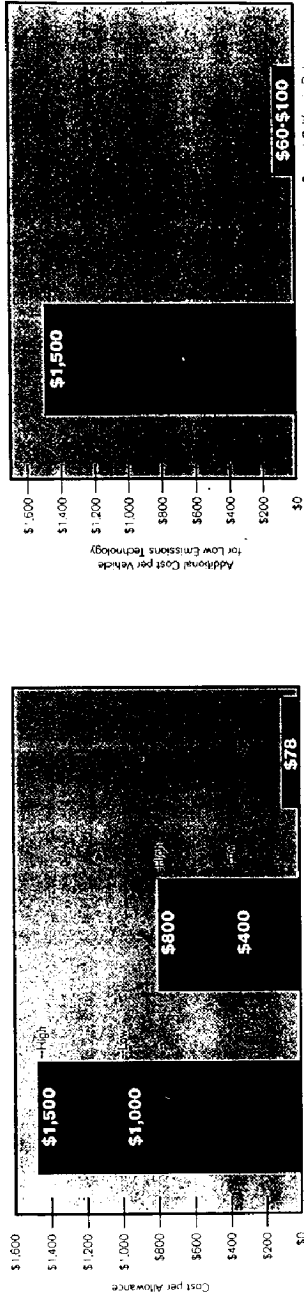
PM2.5 Study -Cities	Approximate Number of People Involved	Adverse Health Effect	Average Annual PM2.5 Concentration ($\mu\text{g}/\text{m}^3$)
Schwartz et al. (1996) -Boston, MA	2,300,000	Short-term Exposures: Premature Mortality	15.7
- St. Louis, MO	2,400,000	Short-term Exposures: Premature Mortality	18.7
-Knoxville, TN	640,000	Short-term Exposures: Premature Mortality	20.8
Thurston et al. (1994) - Toronto, Canada	2,400,000	Short-term Exposures: Hospital Admissions	18.6
Schwartz et al. (1994) -Six Cities study	1,844 Children	Short-term Exposures: Respiratory Symptoms	18.0
Pope et al. (1995) -50 U.S. Cities	300,000	Long-term Exposures: Premature Mortality	18.0
Dockery et al. (1983) -6 U.S. Cities	5,500,00	Long-term Exposures: Premature Mortality	18.0



Cities Studied for PM_{2.5} Data



Costs: Historically Less Than Predicted



RESPONSES BY CAROL BROWNER TO ADDITIONAL QUESTIONS FROM SENATOR CHAFEE

Question 1. During your testimony before the committee on February 12, you referred to several charts and figures. Please provide a copy of each of these charts for the hearing record. Please explain the meaning and source of each statistic used in each chart or figure including a citation to any study from which a statistic was drawn.

Answer. Attached are the charts and figures used by Administrator Browner in her testimony. The meaning and source of the statistics presented in these charts and figures, as well as specific citations, are included as endnotes on the charts and figures.

Question 2. One of the charts used in your testimony was entitled "Smog/Ozone: The Science Calls for Action." This chart (attached) purports to show the number of people in various groups that would be "protected" by the current standard for ozone and by the standard you have proposed. In the context of this chart what does the term "protected" mean?

Answer. The numbers of people "protected," as summarized in the referenced chart (attached), are the numbers of people in the listed groups who live in areas that are not projected to meet the current and proposed ozone standards (based on 1993 to 1995 air quality data). People in these areas would receive increased protection from the standards since they will breathe cleaner air as a result of control measures. As these areas reach attainment with the standards, the level of protection would increase.

Question 3. What are the adverse health effects experienced by "people with respiratory diseases" as the result of exposure to ozone?

Answer. "People with respiratory diseases" are generally subject to the array of adverse health effects related to ozone exposures discussed in the preamble to the proposed ozone NAAQS (especially pages 65719-65723). These adverse effects include decreased lung function; increased respiratory symptoms and related increases in medication use and/or medical treatment; increased airway responsiveness, which can lead to increased medical treatment or to more persistent alterations in airway responsiveness, particularly for individuals with impaired respiratory systems; increased susceptibility to respiratory infection; increased hospital admissions and emergency room visits; and in response to repeated exposures, repeated inflammation of the lung and potential long-term effects that may, over a lifetime, result in chronic respiratory damage.

More specifically, for individuals with respiratory diseases, lung function and symptomatic effects most clearly become adverse at the moderate or greater level of severity. Moderate functional responses (e.g., Forced Expiratory Volume in 1 second or FEV₁ decrements >10 percent but <20 percent, increased nonspecific bronchial responsiveness ≤300 percent, lasting up to 24 hours) and/or moderate symptomatic responses (frequent spontaneous cough, marked discomfort on exercise or deep breath, wheeze accompanied by shortness of breath, lasting up to 24 hours) would likely interfere with normal activity for many such individuals and would likely result in additional or more frequent use of medication. Large functional responses (e.g., FEV₁ decrements ≥20 percent, increased nonspecific bronchial responsiveness >300 percent, lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, persistent wheeze accompanied by shortness of breath, lasting longer than 24 hours) would likely interfere with normal activity for most such individuals and would increase the likelihood of their seeking medical treatment or visiting emergency rooms.

Question 4. If the term "protected" means living in a area that would be designated nonattainment under the current or proposed standard, please indicate how these population estimates were made, including the year for which the estimates are made and a list of the areas that would be in nonattainment for each of the standards.

Answer. The total population estimates in the chart referenced in Question 2 (entitled "Smog/Ozone: The Science Calls for Action") were computed using 1990 U.S. Census data and ambient ozone air quality data from EPA's Aerometric Information Retrieval System (AIRS), the national repository for monitoring data collected by state and local air pollution agencies. Air quality data for the years 1993 through 1995 were used (the three most recent years with complete, quality-assured monitoring data). Based on these data, Table Q-4 lists the counties, and the population in the counties, that failed to meet the three standards referenced in the chart: the current 1-hour, 0.12 ppm, 1 exceedance standard, and the 0.09 ppm and 0.08 ppm average annual third highest daily maximum 8-hour concentration standards. The

determination as to whether a county fails to meet an alternative standard in this analysis was made using the rounding convention used for the current standard; i.e., fractional parts of the design value concentration of 0.005 or greater round up. Of the more than 3000 counties in this country, a total of 561 counties, representing approximately two-thirds of the nation's total population had complete monitoring data used in this analysis.

The 1990 U.S. Census data were used to estimate both total population and the number of children, 18 years of age and younger, living in the counties that failed to meet the referenced alternative standards. The estimated number of asthmatic individuals living in counties that failed to meet each alternative standard was calculated by multiplying the total population living in the counties by the rate of asthma cases in the U.S., obtained from the National Center for Health Statistics document titled "Current Estimates From the National Health Interview Survey, 1994." Similarly, the estimated number of individuals with respiratory diseases living in counties that failed to meet each alternative standard was calculated by multiplying the total population living in the counties by the case rate for chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema, obtained from the same 1994 National Health Interview Survey.

Question 5. The Clean Air Scientific Advisory Committee (CASAC) concluded from a review of all the science that biological responses to ozone may be expected down to background levels. On that basis, please indicate (using the same methodology used to prepare the chart referred to in question 2) the number of people in each group who would be "protected" if you had proposed each of the following standards: 0.08 ppm, 8-hour, 1 exceedance; 0.07 ppm, 8-hour, 1 exceedance; 0.04 ppm, 8-hour, 1 exceedance. How many additional people in each group could be protected if you eliminated the rounding convention that is associated with your proposed standard?

Answer. Table Q-5 provides a summary of the number of people in each group who live in counties that failed to meet the three alternative ozone standards listed in Question 5, as well as the three discussed in the response to Question 4. The Table presents results obtained both by using the current rounding convention, as described in answer to Question 4, and by eliminating the current rounding convention, by rounding up at 0.001 ppm rather than 0.005 ppm. Note that for your requested alternative of 0.04 ppm, the Table simply shows the total population of the counties. There is no reliable evidence regarding adverse health effects at this level.

Question 6. How many people in each group have been left "unprotected" by the standard you have proposed? Is it the additional number that could have been "protected" had you proposed a standard in the current form allowing 1 exceedance per year? Is it the additional number that could have been "protected" had you proposed a standard at the low end of the range (0.07 ppm) that CASAC voted as acceptable? Or is it the number of additional people that could have been "protected" had you followed the science indicating that ozone causes biological responses down to background levels (assuming background is 0.04 ppm)?

Answer. In addition to those people who would be directly protected by implementation measures designed to meet the proposed standard, as discussed in answer to question 11 above, EPA anticipates that additional people would be protected through indirect, regional measures as a result of a shift to broader regional control strategies likely to be incorporated in new implementation plans designed to bring the country into attainment with the proposed standard. Thus, it is difficult to estimate how many more people may actually breathe cleaner air as a result of the proposed standard or any other new 8-hour standard that would trigger such regional strategies. There are approximately 17 million more people (including approximately 4 million children, 1 million asthmatics, and 1 million people with respiratory diseases) who live in areas that are projected not to meet a 0.08 ppm, 1-expected-exceedance, 8-hour standard as compared to the proposed standard.

While there was a consensus on the CASAC ozone panel that the range of consideration could reasonably include an 8-hour standard set at 0.07 ppm, neither the staff nor CASAC has indicated that each level within the range would necessarily be an appropriate choice or meet the statutory requirements. In selecting the proposed standard, the Administrator gave great weight to the individual views of the panel members, none of whom supported the need for a standard at the 0.07 ppm level. Nor does EPA believe at this time (pending review of public comments) that any additional improvements in air quality that would result from a standard at this level are necessary to protect sensitive populations with an adequate margin of safety from adverse effects associated with exposure to ozone.

With regard to any consideration of a standard set at the estimated background level of 0.04 ppm, it is very important to take into account the distinction that the EPA and CASAC have both drawn between "biological responses" and "adverse ef-

fects.” Since NAAQS are not intended to protect people from any and all biological responses, without regard to the nature and severity of such responses, it would be totally inappropriate to characterize the science as suggesting a need for protection of public health at this background level.

Question 7. Considering the case made by the presentation of this chart—that more people can be “protected” (live in nonattainment areas)—if you tighten the standard, what is the reason for not “protecting” those who could have been “protected” with the more stringent alternatives—alternatives that are in keeping with CASAC’s vote on an acceptable range or the underlying science?

Answer. As discussed above in answer to question 6, EPA recognizes that more people would be directly protected by a standard with the same averaging time (8 hours) and level (0.08 ppm) as the proposed standard, but with a 1-expected-exceedance form. In considering the selection of the form of an 8-hour standard, EPA gave great weight to the advice of CASAC. It was, in fact, “the consensus of the [CASAC ozone] Panel that the form of the 8-hour standard be more robust than the present 1-hour standard” (Wolff, 1995), with all ten panel members who expressed their opinions on this issue, including the human health experts, favoring a form that allowed for multiple exceedances. More specifically, the panel endorsed a concentration-based form (e.g., the proposed 3rd-highest daily maximum 8-hour average concentration). Such a form has the effect of insulating areas from the impacts of extreme meteorological events that result in instability in areas’ attainment status and, thus, in control programs designed to bring about long-term improvements in air quality. Thus, in selecting the proposed standard, including the specific averaging time, level, and form, EPA sought to base its decision on the entire range of scientific and technical information that the Clean Air Act specifically identifies as being part of the criteria on which standards are to be based (including “those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant” [Clean Air Act, section 108(a)(2)(A)]), as well as the advice of the independent scientific advisory committee specifically chartered by the Clean Air Act to provide advice and recommendations to the Administrator on NAAQS decisions.

[Attachments to Questions 1, 4, and 5 (From Set 1) From Senator Chafee follow.]

Soot/Particulate Matter The Science Calls For Action

- "It was the consensus of the Panel that although our understanding of the effects of PM is far from complete, the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards."
- "There was also a consensus that a new PM_{2.5} NAAQS be established, with nineteen [of 21] Panel members endorsing the concept of a 24-hour and/or an annual PM_{2.5} NAAQS."
- Individual Panel members endorsed levels within the ranges of:
PM_{2.5} - 15-30 µg/m³ Annual Average
20-≥75 µg/m³ 24-Hour

Source: Clean Air Scientific Advisory Committee (CASAC) Closure on Staff Paper for Particulate Matter;
June 13, 1996



SMOG/OZONE

The Science Calls for Action

CURRENT STANDARD	PROPOSED STANDARD
.12 ppm, 1-hour or .09 ppm, 8-hour	.08 ppm, 8-hour
20 million	33 million
CHILDREN PROTECTED	CHILDREN PROTECTED
4 million	7 million
ASTHMATICS PROTECTED	ASTHMATICS PROTECTED
5 million	8 million
PEOPLE WITH RESPIRATORY DISEASES PROTECTED	PEOPLE WITH RESPIRATORY DISEASES PROTECTED
74 million	122 million
TOTAL AMERICANS PROTECTED	TOTAL AMERICANS PROTECTED



Soot/Particulate Matter The Science Calls For Action

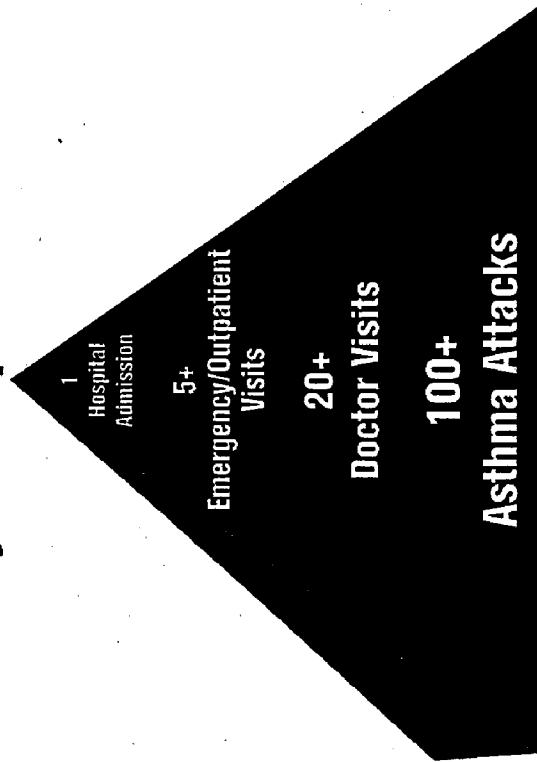
Compared to the current standards:

- 20,000 fewer premature deaths
- 250,000 fewer cases of aggravated asthma
- 250,000 fewer incidences of acute childhood respiratory problems
- 60,000 fewer cases of bronchitis
- 9,000 fewer hospital admissions



Hospital Admissions are the Tip of the Iceberg

For Every 1 Hospital Admission:



Cite: U.S. Department of Health and Human Services (1994) National Hospital Ambulatory Medical Care Survey: 1992 Summary.
The New York Electricity Externality Study (1996) Rowe et al.



Soot/Particulate Matter The Science Calls For Action

PM2.5 Study - Cities	Approximate Number of People Involved	Adverse Health Effect	Average Annual PM2.5 Concentration (µg/m3)
Schwartz et al. (1996) - Boston, MA	2,300,000	Short-term Exposures: Premature Mortality	15.7
- St. Louis, MO	2,400,000	Short-term Exposures: Premature Mortality	18.7
- Knoxville, TN	640,000	Short-term Exposures: Premature Mortality	20.8
Thurston et al. (1994) - Toronto, Canada	2,400,000	Short-term Exposures: Hospital Admissions	18.6
Schwartz et al. (1994) - Six Cities study	1,844 Children	Short-term Exposures: Respiratory Symptoms	18.0
Pope et al. (1995) - 50 U.S. Cities	300,000	Long-term Exposures: Premature Mortality	18.0
Dockery et al. (1993) - 6 U.S. Cities	5,500,00	Long-term Exposures: Premature Mortality	18.0



Cities Studied for PM_{2.5} Data

- Alabama
- Arkansas
- Arizona
- California
- Colorado
- Connecticut
- Washington D.C.
- Florida
- Georgia
- Idaho
- Indiana
- Illinois
- Kansas
- Kentucky
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Nebraska
- North Carolina
- New Jersey
- New Mexico
- Nevada
- New York
- Birmingham
- Mobile
- Little Rock
- Springdale
- Phoenix
- Fresno
- Livermore
- Los Angeles
- Monterey
- San Francisco
- San Jose
- San Rafael
- San Ysidro
- Denver
- Portland
- Portland
- Newtown
- Tampa
- Atlanta
- Boise
- Gary
- Indianapolis
- Chicago
- Topeka
- Wichita
- Morehead
- Watertown
- Detroit
- Minneapolis
- Jackson
- St. Louis
- Omaha
- Charlotte
- Raleigh
- Jersey City
- South Brunswick
- Albuquerque
- Alamo
- Albany
- Buffalo
- New York
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Rhode Island
- South Dakota
- Tennessee
- Texas
- Utah
- Virginia
- Washington
- West Virginia
- British Columbia
- Ontario
- Saskatchewan
- Atton
- Albany
- Cincinnati
- Cleveland
- Dayton
- Steubenville
- Youngstown
- Zanesville
- Oklahoma City
- Portland
- Allegheny
- Penn Hill
- Philadelphia
- State College
- Uniontown
- Providence
- Aberdeen
- Chattanooga
- Hardman
- Hendersonville
- High Point
- Oak Ridge
- Dallas
- El Paso
- Houston
- Salt Lake City
- Utah Valley
- Blackburg
- Charlottesville
- Norfolk
- Seattle
- Spokane
- Takoma
- Charleston
- Huntington
- Parsons
- Penick
- Dunnville
- Egbert
- Washington
- Perth
- Prince George
- Toronto
- Yorkton



Costs: Historically Less Than Predicted

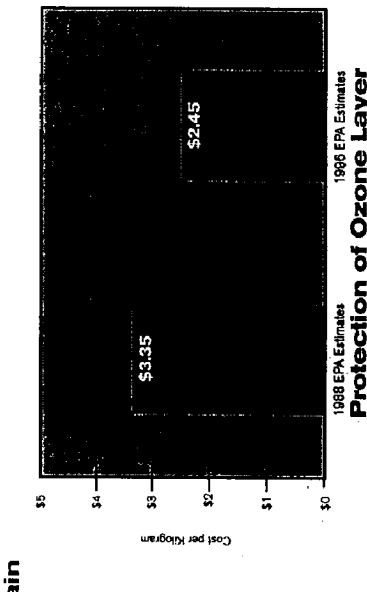
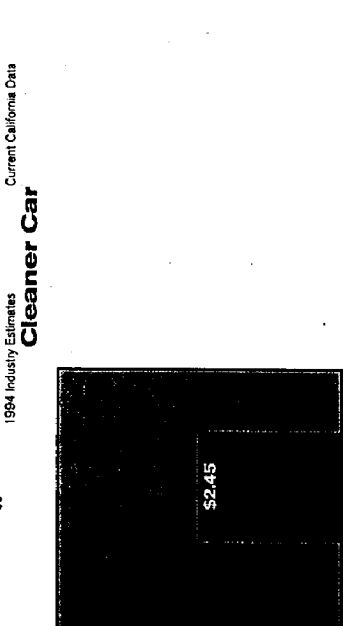
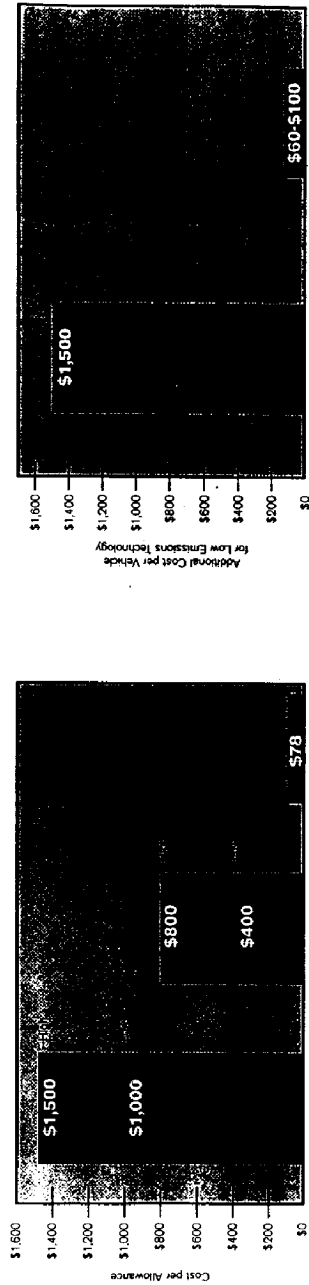


TABLE 0-4. COUNTIES NOT MEETING ALTERNATIVE OZONE NMAQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OBS	STATE	COUNTY	POPULATION	12 PM 1HR 15% SRR M43	08 PPM SRR M43	08 PPM SRR M43
1	AL	CLAY CO	13,252			FAIL
2	AL	COLEBET CO	51,666			FAIL
3	AL	ELMORE CO	23,747			FAIL
4	AL	JEFFERSON CO	651,525	FAIL		FAIL
5	AL	LAWRENCE CO	31,513			FAIL
6	AL	MADISON CO	248,912			FAIL
7	AL	MOBILE CO	208,085			FAIL
8	AL	MOULDER CO	99,358			FAIL
9	AL	SHELBY CO	16,174			FAIL
10	AL	SUMTER CO	8,478			FAIL
11	AK	YUKON-KOTIKUK CA	8,478			FAIL
12	AK	YUKON-KOTIKUK CA	8,478			FAIL
13	AZ	COCHISE CO	2,122,101	FAIL		FAIL
14	AZ	MARICOPA CO	666,880			FAIL
15	AZ	PIMA CO	7,844			FAIL
16	AR	CRITTENDEN CO	49,939			FAIL
17	AR	MONTGOMERY CO	349,660			FAIL
18	AR	WALKER CO	30,039			FAIL
19	AR	PULASKI CO	131,988			FAIL
20	CA	ALAMEDA CO	1,279,182	FAIL		FAIL
21	CA	AMADOR CO	30,039			FAIL
22	CA	BUTTE CO	17,156			FAIL
23	CA	COLUSA CO	16,275			FAIL
24	CA	CONTRA COSTA CO	803,732	FAIL		FAIL
25	CA	DEL NORTE CO	23,460			FAIL
26	CA	EL DORADO CO	52,895			FAIL
27	CA	EL DORADO CO	657,490	FAIL		FAIL
28	CA	GLENN CO	24,798			FAIL
29	CA	IMPERIAL CO	109,303	FAIL		FAIL
30	CA	IMPERIAL CO	109,303	FAIL		FAIL
31	CA	INYO CO	38,281			FAIL
32	CA	KERN CO	138,429			FAIL
33	CA	KINGS CO	101,469			FAIL
34	CA	LAKE CO	50,631			FAIL
35	CA	LOS ANGELES CO	8,863,164	FAIL		FAIL
36	CA	MADERA CO	88,090	FAIL		FAIL
37	CA	MARIN CO	240,028			FAIL
38	CA	MENDOCINO CO	131,102			FAIL
39	CA	MENDOCINO CO	80,345			FAIL
40	CA	MERCED CO	178,403	FAIL		FAIL
41	CA	MONO CO	9,956			FAIL
42	CA	MONTGOMERY CO	326,760			FAIL
43	CA	NEVADA CO	110,760			FAIL
44	CA	NEVADA CO	78,510			FAIL
45	CA	ORANGE CO	2,410,556	FAIL		FAIL
46	CA	PLACER CO	172,796	FAIL		FAIL
47	CA	SACRAMENTO CO	1,043,213	FAIL		FAIL
48	CA	SACRAMENTO CO	1,043,213	FAIL		FAIL
49	CA	SAN BENITO CO	36,697			FAIL
50	CA	SAN BERNARDINO CO	1,418,380	FAIL		FAIL
51	CA	SAN DIEGO CO	2,498,016	FAIL		FAIL
52	CA	SAN FRANCISCO CO	480,628			FAIL
53	CA	SAN JOAQUIN CO	480,628			FAIL
54	CA	SAN LUIS OBISPO CO	217,162			FAIL

TABLE G-4. COUNTIES NOT MEETING ALTERNATIVE OZONE WAGS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OS	STATE	COUNTY	1990 POPULATION	.12 PPM 1HR 1RX	.09 PPM 8HR M3	.08 PPM 8HR M3
55	CA	SAN MATEO CO	649,623			
56	CA	SANTA BARBARA CO	369,608	FAIL	FAIL	FAIL
57	CA	SANTA CLARA CO	1,497,577	FAIL	FAIL	FAIL
58	CA	SANTA CRUZ CO	229,734			
59	CA	SAN JOAQUIN CO	147,036			
60	CA	SILICOON CO	340,421			
61	CA	SOLANO CO	388,222			
62	CA	SONOMA CO	370,522	FAIL	FAIL	FAIL
63	CA	STANISLAUS CO	246,485			
64	CA	SUTTER CO	48,425			
65	CA	TEHAMA CO	48,425			
66	CA	TULARE CO	311,321	FAIL	FAIL	FAIL
67	CA	TUOLUMNE CO	48,456			
68	CA	VENTURA CO	669,016			
69	CA	YUBA CO	147,036			
70	CO	ADAMS CO	265,032	FAIL	FAIL	FAIL
71	CO	ARAPAHOE CO	391,511			
72	CO	BOULDER CO	225,339			
73	CO	DENVER CO	467,610			
74	CO	DOGS CO	397,014			
75	CO	EL PASO CO	397,014			
76	CO	JEFFERSON CO	438,430			FAIL
77	CO	LARIMER CO	186,136			
78	CO	METZOMA CO	18,672			
79	CO	WELD CO	827,645	FAIL	FAIL	FAIL
80	CT	FAIRFIELD CO	827,645			
81	CT	HARTFORD CO	851,781	FAIL	FAIL	FAIL
82	CT	LITCHFIELD CO	174,092	FAIL	FAIL	FAIL
83	CT	MIDDLESEX CO	842,316	FAIL	FAIL	FAIL
84	CT	NEW HAVEN CO	254,957	FAIL	FAIL	FAIL
85	CT	NEW LONDON CO	128,699	FAIL	FAIL	FAIL
86	CT	TOLLAND CO	110,993	FAIL	FAIL	FAIL
87	DE	DELTA CO	44,425	FAIL	FAIL	FAIL
88	DE	NEW CASTLE CO	111,226	FAIL	FAIL	FAIL
89	DE	SUSSEX CO	606,900	FAIL	FAIL	FAIL
90	DC	WASHINGTON	398,978			
91	FL	BREVARD CO	1,235,488			
92	FL	DADE CO	1,235,488			
93	FL	DALLAS CO	1,235,488			
94	FL	DUVAL CO	672,971			
95	FL	ESCAMBIA CO	262,798			
96	FL	HILLSBOROUGH CO	834,054			FAIL
97	FL	LEE CO	235,113			
98	FL	MANATEE CO	677,491			
99	FL	ORANGE CO	107,728			
100	FL	OSCEOLA CO	863,518			
101	FL	PALM BEACH CO	863,518			
102	FL	SEMIOLA CO	863,518			
103	FL	PINELAS CO	405,382			
104	FL	POLK CO	83,829			
105	FL	ST JOHNS CO	277,776			
106	FL	SARASOTA CO	359,359			
107	FL	SPRINGFIELD CO	370,712			
108	FL	VOLUSIA CO	370,712			

TABLE C-4. COUNTIES NOT MEETING ALTERNATIVE OZONE WAJES
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

Obs	State	County	Population 1990	.12 PPM HR 18X	.09 PPM 8HR M3	.08 PPM 8HR M3
109	GA	CHATHAM CO	216,935	FAIL	FAIL	FAIL
110	GA	DE KALB CO	545,837	FAIL	FAIL	FAIL
111	GA	DOUGLAS CO	71,120	FAIL	FAIL	FAIL
112	GA	FANNING CO	45,952	FAIL	FAIL	FAIL
113	GA	GWINNETT CO	648,951	FAIL	FAIL	FAIL
114	GA	SHARPE CO	352,910	FAIL	FAIL	FAIL
115	GA	MUSCOGEE CO	179,278	FAIL	FAIL	FAIL
116	GA	RICHMOND CO	189,719	FAIL	FAIL	FAIL
117	GA	ROCKDALE CO	836,231	FAIL	FAIL	FAIL
118	UT	HONOLULU CO	2,918	FAIL	FAIL	FAIL
119	ID	BUTTE CO	66,090	FAIL	FAIL	FAIL
120	IL	ADAMS CO	173,025	FAIL	FAIL	FAIL
121	IL	CHAMPAIGN CO	57,781,666	FAIL	FAIL	FAIL
122	IL	DECATUR CO	781,666	FAIL	FAIL	FAIL
123	IL	DU PAGE CO	31,704	FAIL	FAIL	FAIL
124	IL	EFFINGHAM CO	20,539	FAIL	FAIL	FAIL
125	IL	JERSEY CO	217,411	FAIL	FAIL	FAIL
126	IL	JOHN CO	183,241	FAIL	FAIL	FAIL
127	IL	MC HENRY CO	117,206	FAIL	FAIL	FAIL
128	IL	MACON CO	47,679	FAIL	FAIL	FAIL
129	IL	MACOUPIN CO	182,429	FAIL	FAIL	FAIL
130	IL	MADISON CO	34,583	FAIL	FAIL	FAIL
131	IL	PRELUD CO	188,723	FAIL	FAIL	FAIL
132	IL	RANDOLPH CO	262,952	FAIL	FAIL	FAIL
133	IL	ROCK ISLAND CO	148,723	FAIL	FAIL	FAIL
134	IL	ST CLAIR CO	262,952	FAIL	FAIL	FAIL
135	IL	ST LOUIS CO	557,313	FAIL	FAIL	FAIL
136	IL	WILL CO	252,913	FAIL	FAIL	FAIL
137	IL	WINNEBAGO CO	300,836	FAIL	FAIL	FAIL
138	IL	WINNEBAGO CO	300,836	FAIL	FAIL	FAIL
139	IN	ALLER CO	157,197	FAIL	FAIL	FAIL
140	IN	CLARK CO	64,404	FAIL	FAIL	FAIL
141	IN	CLAY CO	108,936	FAIL	FAIL	FAIL
142	IN	FLOYD CO	45,527	FAIL	FAIL	FAIL
143	IN	HAMILTON CO	108,936	FAIL	FAIL	FAIL
144	IN	HANCOCK CO	45,527	FAIL	FAIL	FAIL
145	IN	HOUSTON CO	475,594	FAIL	FAIL	FAIL
146	IN	OSHTAGO CO	107,066	FAIL	FAIL	FAIL
147	IN	LA PORTE CO	130,669	FAIL	FAIL	FAIL
148	IN	MADISON CO	130,669	FAIL	FAIL	FAIL
149	IN	MARION CO	797,159	FAIL	FAIL	FAIL
150	IN	MONTGOMERY CO	247,052	FAIL	FAIL	FAIL
151	IN	ST JESSE CO	130,598	FAIL	FAIL	FAIL
152	IN	TIPPECANOE CO	165,058	FAIL	FAIL	FAIL
153	IN	VANDERBURGH CO	106,107	FAIL	FAIL	FAIL
154	IN	VIGO CO	168,767	FAIL	FAIL	FAIL
155	IN	WARRICK CO	327,140	FAIL	FAIL	FAIL
156	IA	LINN CO	150,879	FAIL	FAIL	FAIL
157	IA	POLK CO	150,879	FAIL	FAIL	FAIL
158	IA	SCOTT CO	407,826	FAIL	FAIL	FAIL
159	IA	VAN BUREN CO	407,826	FAIL	FAIL	FAIL
160	IA	WORTHAMPTON CO	161,926	FAIL	FAIL	FAIL
161	KS	SHERMAN CO	161,926	FAIL	FAIL	FAIL
162	KS	WYANDOTTIE CO	161,926	FAIL	FAIL	FAIL

TABLE O-4. COUNTIES NOT MEETING ALTERNATIVE OZONE NAAQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OBS	STATE	COUNTY	1990 POPULATION	.12 PPM 1HR 1EX	.09 PPM 8HR MK3	.08 PPM 8HR MK3
163	KY	BELL CO	31,406			
164	KY	BOONE CO	57,589			
165	KY	BOYD CO	51,150			FAIL
166	KY	BULLITT CO	47,567			FAIL
167	KY	BURKLAND CO	83,866			FAIL
168	KY	CHRISTIAN CO	87,185			FAIL
169	KY	DAVIESS CO	10,157			FAIL
170	KY	EDMONSON CO	225,366			FAIL
171	KY	FRANKLIN CO	35,285			FAIL
172	KY	GRAVES CO	36,740			FAIL
173	KY	GREENUP CO	7,864			FAIL
174	KY	HANCOCK CO	89,240			FAIL
175	KY	HARDIN CO	43,044			FAIL
176	KY	HARRISON CO	68,508			FAIL
177	KY	JEFFERSON CO	30,508		FAIL	
178	KY	JESSAMINE CO	142,031		FAIL	
179	KY	KENTON CO	13,898			
180	KY	LAWRENCE CO	9,062			
181	KY	MADISON CO	9,528			
182	KY	MC CRACKEN CO	33,563			FAIL
183	KY	MC LEAN CO	30,283			FAIL
184	KY	OLDHAM CO	42,583			FAIL
185	KY	PERMIAN CO	23,867			FAIL
186	KY	PULASKI CO	15,145			FAIL
187	KY	SCOTT CO	58,214			FAIL
188	KY	SIMPSON CO	80,083			FAIL
189	KY	WARRIEN CO	248,753			FAIL
190	LA	ACADIANA PAR	168,134			FAIL
191	LA	ANDREUS PAR	380,105			FAIL
192	LA	BEAUREGARD PAR	31,049			FAIL
193	LA	BOSSIER PAR	448,306			FAIL
194	LA	CAJODO PAR	95,860			FAIL
195	LA	CALCASIEU PAR	95,860			FAIL
196	LA	CALCASIEU PAR	142,191			FAIL
197	LA	CALCASIEU PAR	142,191			FAIL
198	LA	IBERVILLE PAR	22,540			FAIL
199	LA	JEFFERSON PAR	31,049			FAIL
200	LA	LAFAYETTE PAR	164,762			FAIL
201	LA	LAFAYETTE PAR	164,762			FAIL
202	LA	LIVINGSTON PAR	95,860			FAIL
203	LA	ORLEANS PAR	496,938			FAIL
204	LA	ORLEANS PAR	496,938			FAIL
205	LA	ORLEANS PAR	142,191			FAIL
206	LA	ORLEANS PAR	142,191			FAIL
207	LA	ST CHARLES PAR	45,637			FAIL
208	LA	ST CHARLES PAR	45,637			FAIL
209	LA	ST JOHN THE BAPTIST PAR	20,879			FAIL
210	LA	ST JOHN THE BAPTIST PAR	39,596			FAIL
211	ME	CUMBERLAND CO	243,133			FAIL
212	ME	HANCOCK CO	58,086			FAIL
213	ME	KENNEBEC CO	115,904			FAIL
214	ME	OXFORD CO	36,310			FAIL
215	ME	OXFORD CO	36,310			FAIL
216	ME	PENOBSCOT CO	146,601			FAIL

TABLE 0-1. COUNTIES NOT MEETING ALTERNATIVE OZONE NADQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OS	STATE	COUNTY	POPULATION	1990 1HR 1X	.12 PPM 8HR M3	.05 PPM 8HR M3	.08 PPM 8HR M3
217	ME	PISCATAQUIS CO	18,653				
218	ME	SAGadahoc CO	33,835	FAIL	FAIL	FAIL	FAIL
219	ME	SOMERSET CO	49,767				
220	ME	WASHINGTON CO	25,809	FAIL	FAIL	FAIL	FAIL
221	ME	YORK CO	45,209	FAIL	FAIL	FAIL	FAIL
222	MD	JANE ARUND EL CO	427,239	FAIL	FAIL	FAIL	FAIL
223	MD	BA LTIMORE CO	692,134	FAIL	FAIL	FAIL	FAIL
224	MD	CARROLL CO	123,372	FAIL	FAIL	FAIL	FAIL
225	MD	C ECIL CO	71,847	FAIL	FAIL	FAIL	FAIL
226	MD	CHESAPEAKE CO	101,154	FAIL	FAIL	FAIL	FAIL
227	MD	HARFORD CO	182,132	FAIL	FAIL	FAIL	FAIL
228	MD	KENT CO	17,842	FAIL	FAIL	FAIL	FAIL
229	MD	MONTGOMERY CO	757,027	FAIL	FAIL	FAIL	FAIL
230	MD	PRINCE GEORGES CO	1,188,888	FAIL	FAIL	FAIL	FAIL
231	MD	ST. MARYS CO	756,014	FAIL	FAIL	FAIL	FAIL
232	MA	BARNSTABLE CO	186,605	FAIL	FAIL	FAIL	FAIL
233	MA	BERKSHIRE CO	139,352	FAIL	FAIL	FAIL	FAIL
234	MA	BRISTOL CO	506,325	FAIL	FAIL	FAIL	FAIL
235	MA	ESSEX CO	1,188,888	FAIL	FAIL	FAIL	FAIL
236	MA	HAMPDEN CO	456,310	FAIL	FAIL	FAIL	FAIL
237	MA	HAMP SHIRE CO	146,568	FAIL	FAIL	FAIL	FAIL
238	MA	MIDDLESEX CO	1,398,468	FAIL	FAIL	FAIL	FAIL
239	MA	PLYMOUTH CO	435,276	FAIL	FAIL	FAIL	FAIL
240	MA	SUFFOLK CO	778,777	FAIL	FAIL	FAIL	FAIL
241	MA	WORCESTER CO	709,705	FAIL	FAIL	FAIL	FAIL
242	MI	ALLEGAN CO	90,509	FAIL	FAIL	FAIL	FAIL
243	MI	BENZIE CO	12,200	FAIL	FAIL	FAIL	FAIL
244	MI	BERRIEN CO	161,378	FAIL	FAIL	FAIL	FAIL
245	MI	CALHOUN CO	45,888	FAIL	FAIL	FAIL	FAIL
246	MI	CLINTON CO	57,883	FAIL	FAIL	FAIL	FAIL
247	MI	GENEESE CO	430,459	FAIL	FAIL	FAIL	FAIL
248	MI	HURON CO	34,951	FAIL	FAIL	FAIL	FAIL
249	MI	INGHAM CO	281,912	FAIL	FAIL	FAIL	FAIL
250	MI	KALAMAZOO CO	500,631	FAIL	FAIL	FAIL	FAIL
251	MI	LENAPEE CO	91,476	FAIL	FAIL	FAIL	FAIL
252	MI	MACOMB CO	717,400	FAIL	FAIL	FAIL	FAIL
253	MI	MALDEN CO	25,537	FAIL	FAIL	FAIL	FAIL
254	MI	MASON CO	1,083,592	FAIL	FAIL	FAIL	FAIL
255	MI	OSHTON CO	1,083,592	FAIL	FAIL	FAIL	FAIL
256	MI	OAKLAND CO	1,187,768	FAIL	FAIL	FAIL	FAIL
257	MI	OTTAWA CO	187,768	FAIL	FAIL	FAIL	FAIL
258	MI	ST. CLAIR CO	145,607	FAIL	FAIL	FAIL	FAIL
259	MI	WASHTENAW CO	282,927	FAIL	FAIL	FAIL	FAIL
260	MI	WAYNE CO	2,243,641	FAIL	FAIL	FAIL	FAIL
261	MI	ANOKA CO	275,227	FAIL	FAIL	FAIL	FAIL
262	MN	DAKOTA CO	16,239	FAIL	FAIL	FAIL	FAIL
263	MN	KOOCHICING CO	15,856	FAIL	FAIL	FAIL	FAIL
264	MN	LAKE CO	14,856	FAIL	FAIL	FAIL	FAIL
265	MS	ANDERSON CO	35,356	FAIL	FAIL	FAIL	FAIL
266	MS	ADAMS CO	67,910	FAIL	FAIL	FAIL	FAIL
267	MS	DE SOTO CO	8,377	FAIL	FAIL	FAIL	FAIL
268	MS	FRANKLIN CO	8,377	FAIL	FAIL	FAIL	FAIL
269	MS	HANCOCK CO	1,481	FAIL	FAIL	FAIL	FAIL
270	MS	HINDS CO	244,441	FAIL	FAIL	FAIL	FAIL

TABLE G-4. COUNTIES NOT MEETING ALTERNATIVE OZONE STANDARDS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OBS	STATE	COUNTY	1990 POPULATION	.12 PPM 1HR 1EX	.09 PPM 8HR M3	.08 PPM 8HR M3
271	MS	JACKSON CO	115,243			
272	MS	LAUDERDALE CO	75,555			
273	MS	LEE CO	65,581			
274	MS	MASTIC CO	57,784			
275	MS	SHARKEY CO	47,880			
276	MS	WARREN CO	153,411			
277	MO	CLAY CO	207,549	FAIL	FAIL	FAIL
278	MO	JACKSON CO	171,380			
279	MO	JEFFERSON CO	9,104	FAIL	FAIL	FAIL
280	MO	MONROE CO	57,867			
281	MO	PLATTE CO	232,507	FAIL	FAIL	FAIL
282	MO	WARREN CO	386,685	FAIL	FAIL	FAIL
283	MO	ST LOUIS CO	416,444			
284	MO	ST LOUIS CO	213,641			
285	MO	ST LOUIS CO	213,641			
286	NE	DOUGLAS CO	27,437			
287	NE	LANCASTER CO	254,667			
288	NE	DOUGLAS CO	9,264			
289	NV	WASHOE CO	70,121			
290	NV	WHITE PINE CO	120,005			
291	NV	WHITE PINE CO	120,005			
292	NH	HILLSBOROUGH CO	245,845	FAIL	FAIL	FAIL
293	NH	MERRIMACK CO	38,552			
294	NH	ROCKINGHAM CO	254,327			
295	NH	SULLIVAN CO	502,824			
296	NH	SULLIVAN CO	138,053			
297	NH	SULLIVAN CO	778,206			
298	NJ	BERGEN CO	552,055			
299	NJ	BERGEN CO	552,055			
300	NJ	CAMDEN CO	107,776			
301	NJ	CUMBERLAND CO	325,824			
302	NJ	ESSEX CO	671,780			
303	NJ	HUDSON CO	421,353			
304	NJ	HUDSON CO	421,353			
305	NJ	HUNTERDON CO	433,203			
306	NJ	MERCER CO	493,819			
307	NJ	MORRIS CO	450,577			
308	NJ	MORRIS CO	450,577			
309	NJ	OCEAN CO	63,319			
310	NJ	UNION CO	45,235			
311	NM	SAN JUAN CO	282,594			
312	NM	SANDOVAL CO	1,103,895			
313	NM	SANDOVAL CO	1,103,895			
314	NM	VALENCIA CO	95,195			
315	NY	ALBANY CO	259,462			
316	NY	ALBANY CO	259,462			
317	NY	CHAUTAUGUA CO	968,532			
318	NY	CHAUTAUGUA CO	968,532			
319	NY	CHEMUNG CO	37,275			
320	NY	DUTCHESS CO	65,797			
321	NY	DUTCHESS CO	65,797			
322	NY	ESSEX CO	110,943			
323	NY	ESSEX CO	110,943			
324	NY	HERKIMER CO				
325	NY	JEFFERSON CO				

TABLE Q-4. COUNTIES NOT MEETING ALTERNATIVE OZONE WAQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OBS	STATE	COUNTY	1990			.08 PPM 8HR M03
			POPULATION	.12 PPM 1HR 1RX	.09 PPM 8HR M03	
325	NY	KINGS CO	2,300,564		FAIL	
326	NY	MONROE CO	69,120		FAIL	
327	NY	MONROE CO	713,968		FAIL	
328	NY	NIAGARA CO	220,756		FAIL	
329	NY	ONEIDA CO	48,976		FAIL	
330	NY	OSWEGO CO	307,647		FAIL	
331	NY	PUTNAM CO	83,941	FAIL	FAIL	
332	NY	QUEENS CO	1,953,576	FAIL	FAIL	
333	NY	RICHMOND CO	181,276	FAIL	FAIL	
334	NY	SCHENECTADY CO	149,285	FAIL	FAIL	
335	NY	SCHENECTADY CO	1,321,864	FAIL	FAIL	
336	NY	SUFFOLK CO	89,123	FAIL	FAIL	
337	NY	SUFFOLK CO	89,123	FAIL	FAIL	
338	NY	UNSTEAD CO	87,123	FAIL	FAIL	
339	NY	UNSTEAD CO	87,123	FAIL	FAIL	
340	NY	WESTCHESTER CO	874,866	FAIL	FAIL	
341	NC	ALEXANDER CO	174,821		FAIL	
342	NC	BUNCOMBE CO	77,843		FAIL	
343	NC	BUNCOMBE CO	77,843		FAIL	
344	NC	CANDLER CO	70,709		FAIL	
345	NC	CANDLER CO	5,904		FAIL	
346	NC	CASWELL CO	20,693		FAIL	
347	NC	CHATHAM CO	38,752		FAIL	
348	NC	CHATHAM CO	38,752		FAIL	
349	NC	CHATHAM CO	38,752		FAIL	
350	NC	DURHAM CO	27,859		FAIL	
351	NC	DURHAM CO	181,835		FAIL	
352	NC	DURHAM CO	256,414		FAIL	
353	NC	DURHAM CO	256,414		FAIL	
354	NC	GRAVILL CO	38,345		FAIL	
355	NC	GUILFORD CO	347,420		FAIL	
356	NC	HAYWOOD CO	46,342		FAIL	
357	NC	JOHNSON CO	81,319		FAIL	
358	NC	MARTIN CO	50,319		FAIL	
359	NC	MARTIN CO	25,078		FAIL	
360	NC	MECKLENBURG CO	511,433		FAIL	
361	NC	NEW HANOVER CO	120,788		FAIL	
362	NC	PERSON CO	30,180		FAIL	
363	NC	PERSON CO	30,180		FAIL	
364	NC	ROCKINGHAM CO	107,924		FAIL	
365	NC	ROCKINGHAM CO	86,064		FAIL	
366	NC	ROCKINGHAM CO	86,064		FAIL	
367	NC	WAKE CO	111,268		FAIL	
368	NC	WAKE CO	423,380		FAIL	
369	NC	YANCEY CO	15,419		FAIL	
370	ND	MC KENZIE CO	6,383		FAIL	
371	ND	MC KENZIE CO	6,383		FAIL	
372	ND	WELLS CO	2,381		FAIL	
373	ND	WELLS CO	2,381		FAIL	
374	OH	ALLEN CO	109,755		FAIL	
375	OH	ASHTABULA CO	281,472		FAIL	
376	OH	CLARK CO	147,548		FAIL	
377	OH	CLARK CO	147,548		FAIL	
378	OH	CLERMONT CO	150,187		FAIL	

TABLE Q-4. COUNTIES NOT MEETING ALTERNATIVE OZONE NMAQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OBS	STATE	COUNTY	1990 POPULATION	12 PM 1HR 15X	08 PM 8HR MX3	08 PM 8HR MX3
379	OH	CLINTON CO	35,415		FAIL	FAIL
380	OH	COLUMBUS CO	1,422,140		FAIL	FAIL
381	OH	FRANKLIN CO	1,217,150		FAIL	FAIL
382	OH	HAMILTON CO	866,258		FAIL	FAIL
383	OH	JEFFERSON CO	80,238		FAIL	FAIL
384	OH	KNOX CO	47,473		FAIL	FAIL
385	OH	LANCASTER CO	23,499		FAIL	FAIL
386	OH	LAWRENCE CO	138,300		FAIL	FAIL
387	OH	LICKING CO	42,310		FAIL	FAIL
388	OH	LOGAN CO	271,136		FAIL	FAIL
389	OH	LORAIN CO	487,364		FAIL	FAIL
390	OH	MADISON CO	57,364		FAIL	FAIL
391	OH	MAHONING CO	264,806		FAIL	FAIL
392	OH	MEDINA CO	122,354		FAIL	FAIL
393	OH	Miami	93,182		FAIL	FAIL
394	OH	MIAMI CO	53,182		FAIL	FAIL
395	OH	MONROE CO	122,354		FAIL	FAIL
396	OH	PORTAGE CO	142,582		FAIL	FAIL
397	OH	PERLE CO	40,113		FAIL	FAIL
398	OH	STARK CO	367,585		FAIL	FAIL
399	OH	SUMMIT CO	534,990		FAIL	FAIL
400	OH	TALMADGE CO	244,000		FAIL	FAIL
401	OH	TUSCARAWAS CO	84,000		FAIL	FAIL
402	OH	WARREN CO	113,909	FAIL	FAIL	FAIL
403	OH	WASHINGTON CO	62,254		FAIL	FAIL
404	OH	WYANDOT CO	174,253		FAIL	FAIL
405	OK	CLEVELAND CO	132,582			
406	OK	DEKALB CO	132,582			
407	OK	MC CLAIN CO	599,611			
408	OK	OKLAHOMA CO	599,611			
409	OR	TULSA CO	593,341			
410	OR	CLATSOP CO	278,850			
411	OR	CLATSOP CO	278,850			
412	OR	JACKSON CO	146,378			
413	OR	LANE CO	282,912			
414	PA	ALLEGHENY CO	1,336,449	FAIL	FAIL	FAIL
415	PA	BERKELEY CO	186,093			
416	PA	BLAIR CO	130,542			
417	PA	BUCKS CO	541,174	FAIL	FAIL	FAIL
418	PA	CAMBERIA CO	163,029			
419	PA	DELFWARE CO	237,813			
420	PA	DELFWARE CO	237,813			
421	PA	ERIE CO	275,572	FAIL	FAIL	FAIL
422	PA	LACKAWANNA CO	219,039			
423	PA	LANCASTER CO	422,822			
424	PA	LEHIGH CO	36,746			
425	PA	LUZERNE CO	328,149			
426	PA	LUZERNE CO	328,149			
427	PA	LYCOMING CO	118,710			
428	PA	MERCER CO	121,003			
429	PA	MONTGOMERY CO	678,111	FAIL	FAIL	FAIL
430	PA	NORTHAMPTON CO	41,192			
431	PA	PERRY CO	41,192			
432	PA	PHILADELPHIA CO	1,585,577	FAIL	FAIL	FAIL

TABLE Q-4. COUNTIES NOT MEETING ALTERNATIVE OZONE NMAQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OBS	STATE	COUNTY	1990 POPULATION	12 RPM 1HR 1EQ	09 RPM 8HR M23	08 RPM 8HR M23
433	PA	WASHINGTON CO	204,584		FAIL	FAIL
434	PA	WESTMORELAND CO	370,321		FAIL	FAIL
435	PA	YORK CO	161,135		FAIL	FAIL
436	RI	KENT CO	161,135	FAIL	FAIL	FAIL
437	RI	PROVIDENCE CO	596,270	FAIL	FAIL	FAIL
438	SC	ABBEVILLE CO	22,862			
439	SC	AIKEN CO	120,150			
440	SC	ANDERSON CO	120,150			
441	SC	BERNHELL CO	20,293			
442	SC	BERKELEY CO	128,776		FAIL	FAIL
443	SC	CHARLESTON CO	295,039			
444	SC	CHEROKEE CO	34,126			
445	SC	CHEROKEE CO	34,126			
446	SC	DARLINGTON CO	61,851			
447	SC	EDGEFIELD CO	18,375			
448	SC	OCONEE CO	57,494			
449	SC	SPARTANBURG CO	285,720			
450	SC	RICHLAND CO	285,720			
451	SC	SPARTANBURG CO	226,800			
452	SC	UNION CO	30,137			
453	SC	UNION CO	36,815			
454	SC	WILLIAMSBURG CO	168,250			
455	TN	ANDERSON CO	85,969		FAIL	FAIL
456	TN	BLOUNT CO	73,712		FAIL	FAIL
457	TN	BRADLEY CO	50,789			
458	TN	COFFEE CO	50,789			
459	TN	DEKALB CO	50,789			
460	TN	DICKSON CO	35,061		FAIL	FAIL
461	TN	DYER CO	34,854			
462	TN	HAMBLER CO	50,480			
463	TN	HAMILTON CO	285,335			
464	TN	JEFFERSON CO	33,016			
465	TN	JEFFERSON CO	33,016		FAIL	FAIL
466	TN	KNOX CO	335,749			
467	TN	MADISON CO	77,882			
468	TN	MADISON CO	77,882			
469	TN	MURFREESBORO CO	118,576			
470	TN	SEVIER CO	51,043			
471	TN	SHELBY CO	826,330	FAIL	FAIL	FAIL
472	TN	SULLIVAN CO	143,596		FAIL	FAIL
473	TN	SMITH CO	83,021		FAIL	FAIL
474	TN	WILKINSON CO	83,021		FAIL	FAIL
475	TN	WILSON CO	67,675			
476	TX	BEXAR CO	1,185,394			
477	TX	BRAZORIA CO	191,707	FAIL	FAIL	FAIL
478	TX	BRAZORIA CO	191,707			
479	TX	CAMERON CO	260,120			
480	TX	COLLIN CO	264,036	FAIL	FAIL	FAIL
481	TX	DALLAS CO	1,852,810	FAIL	FAIL	FAIL
482	TX	DENTON CO	273,525	FAIL	FAIL	FAIL
483	TX	EL PASO CO	217,399	FAIL	FAIL	FAIL
484	TX	GALVESTON CO	217,399	FAIL	FAIL	FAIL
485	TX	GREGG CO	104,948	FAIL	FAIL	FAIL
486	TX	HARRIS CO	2,818,199	FAIL	FAIL	FAIL

TABLE Q-4. COUNTIES NOT MEETING ALTERNATIVE OZONE NAAQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OS	STATE	COUNTY	1990 POPULATION	.12 PPM 1HR 1EX	.05 PPM 8HR MX3	.08 PPM 8HR MX3
487	TX	JERFERTSON CO	239,397	FAIL	FAIL	FAIL
488	TX	NUECES CO	231,145	FAIL	FAIL	FAIL
489	TX	ORANGE CO	80,509	FAIL	FAIL	FAIL
490	TX	SMITH CO	151,309	FAIL	FAIL	FAIL
491	TX	TARRANT CO	1,576,407	FAIL	FAIL	FAIL
492	TX	TRAVIS CO	74,361	FAIL	FAIL	FAIL
493	TX	VICTORIA CO	187,941	FAIL	FAIL	FAIL
494	UT	DAVIS CO	187,941	FAIL	FAIL	FAIL
495	UT	SALT LAKE CO	725,956	FAIL	FAIL	FAIL
496	UT	SPRING VALLEY CO	245,920	FAIL	FAIL	FAIL
497	UT	UTAH CO	245,920	FAIL	FAIL	FAIL
498	UT	WREER CO	188,330	FAIL	FAIL	FAIL
499	VT	BENNINGTON CO	35,845	FAIL	FAIL	FAIL
500	VT	CHITTENDEN CO	170,956	FAIL	FAIL	FAIL
501	VA	ARLINGTON CO	170,956	FAIL	FAIL	FAIL
502	VA	AUGUSTA CO	54,677	FAIL	FAIL	FAIL
503	VA	CAROLINE CO	19,217	FAIL	FAIL	FAIL
504	VA	CHARLES CITY CO	206,722	FAIL	FAIL	FAIL
505	VA	CHARLES COUNTY CO	206,722	FAIL	FAIL	FAIL
506	VA	FAIRFAX CO	818,584	FAIL	FAIL	FAIL
507	VA	FALQUIER CO	48,741	FAIL	FAIL	FAIL
508	VA	FREDERICK CO	45,723	FAIL	FAIL	FAIL
509	VA	HANOVER CO	217,881	FAIL	FAIL	FAIL
510	VA	HENRY CO	56,942	FAIL	FAIL	FAIL
511	VA	HENRY CO	56,942	FAIL	FAIL	FAIL
512	VA	MADISON CO	11,949	FAIL	FAIL	FAIL
513	VA	PRINCE WILLIAM CO	213,686	FAIL	FAIL	FAIL
514	VA	SPOTSYLDEN CO	217,881	FAIL	FAIL	FAIL
515	VA	STAFFORD CO	61,236	FAIL	FAIL	FAIL
516	VA	WARREN CO	26,142	FAIL	FAIL	FAIL
517	VA	WYTHE CO	25,466	FAIL	FAIL	FAIL
518	VA	YAMHOUBA CO	133,731	FAIL	FAIL	FAIL
519	VA	YAMHOUBA CO	133,731	FAIL	FAIL	FAIL
520	VA	HAMPTON CO	133,731	FAIL	FAIL	FAIL
521	VA	SUFFOLK CO	52,141	FAIL	FAIL	FAIL
522	VA	CLALLAM CO	56,464	FAIL	FAIL	FAIL
523	VA	CLARK CO	239,053	FAIL	FAIL	FAIL
524	VA	PIERCE CO	586,203	FAIL	FAIL	FAIL
525	WA	SNOHOMISH CO	485,642	FAIL	FAIL	FAIL
526	WA	SPOKANE CO	361,364	FAIL	FAIL	FAIL
527	WA	WACATAWA CO	156,827	FAIL	FAIL	FAIL
528	WV	CABELL CO	34,653	FAIL	FAIL	FAIL
529	WV	GREENBERGER CO	34,653	FAIL	FAIL	FAIL
530	WV	HANCOCK CO	35,233	FAIL	FAIL	FAIL
531	WV	KANAWHA CO	207,639	FAIL	FAIL	FAIL
532	WV	PUTNAM CO	86,915	FAIL	FAIL	FAIL
533	WV	WOOD CO	86,915	FAIL	FAIL	FAIL
534	MI	BROWN CO	194,594	FAIL	FAIL	FAIL
535	MI	COLUMBIA CO	45,088	FAIL	FAIL	FAIL
536	MI	DOUGLASS CO	376,559	FAIL	FAIL	FAIL
537	MI	DODGE CO	376,559	FAIL	FAIL	FAIL
538	MI	DOOR CO	25,690	FAIL	FAIL	FAIL
539	MI	FLORENCE CO	4,580	FAIL	FAIL	FAIL
540	MI	POND DU LAC CO	90,083	FAIL	FAIL	FAIL

TABLE O-4. COUNTIES NOT MEETING ALTERNATIVE OZONE MAQS
(BASED ON 1993-95 AMBIENT OZONE AIR QUALITY DATA FROM AIRS)

OBS	STATE	COUNTY	1990 POPULATION	12 PM 1HR IEQ	.05 PPM 8HR M3	.08 PPM 8HR M3
541	WI	JEFFERSON CO	67,783			
542	WI	KENOSHA CO	128,181	FAIL	FAIL	FAIL
543	WI	MANITOWISH CO	88,888	FAIL	FAIL	FAIL
544	WI	MANITOWOC CO	80,421	FAIL	FAIL	FAIL
545	WI	MARATHON CO	115,400	FAIL	FAIL	FAIL
546	WI	MILWAUKEE CO	959,275	FAIL	FAIL	FAIL
547	WI	ONEIDA CO	11,519			
548	WI	OSHAUWEE CO	14,519			
549	WI	OZAUKEE CO	72,831	FAIL	FAIL	FAIL
550	WI	POLK CO	34,773			
551	WI	RACINE CO	175,034			
552	WI	ROCK CO	159,240			
553	WI	SABINE CO	50,243			
554	WI	SAUK CO	46,975			
555	WI	SHEBOYGAN CO	103,877			
556	WI	VERNON CO	25,617			
557	WI	WASHINGTON CO	95,328			
558	WI	WAUKESHA CO	304,715			
559	WI	WINNEBAGO CO	140,320			
560	WI	WINNEBAGO CO	11,172			
561	WY	TETON CO	11,172			
			*****	*****	*****	*****
			165,865,292	106	136	335

Table Q-5. Number of People Living in Counties Not Meeting the Current 1-hour 0.12 ppm Ozone NAAQS and Alternative 8-hour Ozone Standards (based on 1993-1995 air quality data)

Averaging Time	Level of the Standard	Form of the Standard	Millions of People Living in Counties Not Meeting Alternative Standards -- based on current rounding convention				Additional Millions of People Living in Counties Not Meeting Alternative Standards -- based on Rounding Up at 0.001 ppm			
			Total	Children	Asthmatics	Respiratory Diseases	Total	Children	Asthmatics	Respiratory Diseases
1-hour	0.12 ppm	1 expected exceedance	74	20	4	5	10	3	0.6	0.6
			75	20	4	5	26	5	1	2
8-hour	0.09 ppm	average 3rd highest	122	33	7	8	13	5	0.7	0.8
		1 expected exceedance	139	37	8	9	9	7	0.5	0.6
		1 expected exceedance	159	43	9	10	2	1	0.1	0.1
	0.04 ppm	1 expected exceedance	166	44	9	10	0	0	0	0
Population Total for all 561 Counties with Monitors			166							

Question 8. Section 109(b)(1) of the Clean Air Act requires you to promulgate national ambient air quality standards “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and *allowing an adequate margin of safety*, are requisite to protect public health.” Do the standards you have proposed provide an adequate margin of safety? Please identify the margin of safety that is provided.

Answer. Based on the record before the Agency at the time of proposal, including the advice and recommendations of the CASAC panels, the Administrator concluded—subject to further consideration based on public comments—that the proposed standards were requisite to protect the public health with an adequate margin of safety. The Administrator will of course re-examine that conclusion in light of public comments in making her final decision.

In selecting primary standards that provide an adequate margin of safety, the Agency is seeking to prevent pollution levels that pose an unacceptable risk of harm. In selecting the proposed standards, the Administrator did not follow what might be called a two-step process, involving an initial determination of a “safe” or “protective” level, followed by the addition of a discrete margin of safety to that level. Instead, consistent with EPA’s decisions over the years, the Administrator considered in the course of her analysis such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and nature of uncertainties that must be addressed. As EPA indicated in revising the standards for particulate matter in 1987 (52 FR 24641, July 1, 1987):

In the absence of clearly identified thresholds for health effects, the selection of a standard that provides an adequate margin of safety requires an exercise of informed judgment by the Administrator. The level selected will depend on the expected incidence and severity of the potential effects and on the size of the population at risk, as well as on the degree of scientific certainty that the effects will in fact occur at any given level of pollution. For example, if a suspected but uncertain health effect is severe and the size of the population at risk is large, a more cautious approach will be appropriate than would be if the effect were less troubling or the exposed population smaller.

This approach is consistent with the advice and recommendations of CASAC on the current review of the standards for ozone and particulate matter, as well as its advice from previous reviews. It is also consistent with judicial decisions specifically interpreting the margin of safety requirement in section 109(b)(1) of the Act. In upholding EPA’s national air quality standards for lead, for example, the U.S. Court of Appeals for the District of Columbia Circuit stated:

Adding the margin of safety at the end of the analysis is one approach, but it is not the only possible method. Indeed, the Administrator considered this approach but decided against it because of complications raised by multiple sources of lead exposure. The choice between these possible approaches is a policy choice of the type that Congress specifically left to the Administrator’s judgment. This court must allow him the discretion to determine which approach will best fulfill the goals of the Act.

Lead Industries Association v. EPA, 647 F.2d 1130, 1161–62 (D.C. Cir.), *cert. denied* 449 U.S. 1042 (1980) (footnotes and citations omitted). See also *Natural Resources Defense Council v. Administrator*, 902 F.2d 962, 973–74 (D.C. Cir. 1990) (PM NAAQS), *vacated, in part, dismissed*, 921 F.2d 326 (D.C. Cir.), *certs. dismissed*, 498 U.S. 1075, *cert. denied*, 498 U.S. 1082 (1991); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186–87 (D.C. Cir. 1981) (ozone NAAQS), *cert. denied*, 455 U.S. 1034 (1982).

In summary, the Agency’s approach to providing an adequate margin of safety in the proposed standards for ozone and particulate matter did not involve the addition of a specific increment of protection at the end of the analytic process. Rather, the considerations that go into selecting a standard that provides an adequate margin of safety were taken into account as appropriate at various stages of the analytic process, both by the CASAC in offering its advice to the Administrator and by the Administrator in selecting the specific standards that she proposed.

Question 9. In your testimony on February 12, you stated, “The standards that we proposed in keeping with the requirements of the law are designed to guard against and prevent those premature deaths. Because it is death, because it is so severe, we do it with a margin of safety, as the law directs us to.” Would the standard for fine particulate matter that you have proposed eliminate all premature deaths that may be expected to be caused by exposure to this pollutant or would

some premature deaths continue as the result of breathing air that met the standards you have proposed?

Answer. The Administrator has based her proposal on a full evaluation of peer reviewed scientific information on the known and potential effects of PM, not on the results of a national assessment of the potential number of premature deaths at alternative levels. EPA's assessment of the science, consistent with the advice of CASAC, concludes that the current information base does not enable us to demonstrate or quantify adverse effects at levels below our proposed standards with any degree of reasonable certainty. That assessment of the recent scientific literature does find a consistent and coherent set of studies that indicate clear relationships between PM and health effects at concentrations below those permitted by the current PM standards. Nevertheless, as the preamble recognizes, key uncertainties and related issues increasingly call into question the likelihood of PM-related effects as PM_{2.5} concentrations decrease below the mean values in areas where effects have been observed and/or as such concentrations approach background levels (61 FR 65659). These uncertainties and unanswered questions, particularly with respect to biological mechanisms, have led some to suggest PM_{2.5} standards at levels higher than those proposed. By contrast, the Administrator proposed to include a greater margin of safety, in part because the potential effects are so severe. As detailed in the preamble, this led to proposal of an annual PM_{2.5} standard at a level below the lowest mean values in areas where such associations were clearly observed.

Based on the record before the Agency at the time of proposal, the Administrator concluded that it is neither demonstrated nor likely that significant adverse health effects would occur at PM_{2.5} concentrations below those levels that would result from attainment of the proposed standards. Consistent with other NAAQS decisions, however, the margin of safety inherent in the approach taken by the Administrator does not result in a standard with zero risk. If the key uncertainties inherent in the epidemiological data base at the lowest range of concentrations examined are discounted, quantitative estimates can be made of potential effects at concentrations that extend to the lowest levels measured in the studies. Although such estimates may be consistent with the study results, they reflect only one of several possible outcomes, especially at such lower concentrations. Even at concentrations where the evidence for the existence of PM effects is stronger, the quantitative certainty to be accorded such risk estimates is unclear. Because the scientific evidence does not demonstrate whether or not any increased mortality is occurring at such lower concentrations, such estimates should be viewed with caution.

Question 10. If premature deaths and numbers of other serious adverse health effects would be caused by fine particulate pollution at ambient levels in compliance with the standard you have proposed, how does the standard provide a margin of safety?

Answer. See responses to Questions 8 and 9 above.

Question 11. Although the Staff Paper stated that no studies relying on human data indicate premature deaths from exposure to ozone pollution at ambient levels, the draft Regulatory Impact Analysis released with the proposed standard did include avoided deaths among the benefits estimated for the proposed ozone standard. Please provide the foundation for this estimated benefit. What studies did you rely on to make the estimates? How many deaths are caused by ozone exposures at what levels? Would deaths be caused by ambient ozone levels below the standard you have proposed? How many deaths at each level of the following levels: current standard; proposed standard; .07 ppm, 8-hour, 1 exceedance; and background (.04 ppm)?

Answer. Although the Staff Paper noted a number of epidemiologic studies cited in the Criteria Document that suggested a possible association of ozone with mortality, both the Criteria Document and the Staff Paper pointed out flaws and limitations in the available literature. The Criteria Document and Staff Paper ultimately concluded "that although an association between ambient O₃ exposure in areas with very high O₃ levels and daily mortality has been suggested, the strength of any such association remains unclear at this time" (Staff Paper, p. 42). Accordingly, the potential association between ozone and mortality does not form a principal basis for the proposed ozone standard.

The current draft Ozone Regulatory Impact Analysis (RIA) reflects an analytical attempt to quantify all of the known and potential benefits of reducing ozone. As noted in the RIA, a number of such benefit categories cannot be quantified with available information. In an attempt to capture a full range of potential benefits of reducing ozone, including more uncertain and speculative benefits for inclusion in upper bound estimates, the RIA staff examined the ozone mortality issue. This examination includes several peer reviewed studies that have appeared in the lit-

erature since publication of the Criteria Document. Given the inherent uncertainties involved in such estimates, they were used only in expressing an upper bound benefits estimate; the lower bound for ozone mortality benefits was zero.

The ozone RIA is not the only benefits assessment to take this approach. A study sponsored by the Economic Commission for Europe (EFTEC Ltd, 1996) provided a range of estimates for ozone-mortality based on earlier studies contained in the Ozone Criteria Document. In addition to these, the RIA analysis also examined more recently published multi-pollutant community studies addressing ozone mortality that were evaluated in the Particulate Matter Criteria Document. As noted on page IX-6 of the RIA, these include studies in several U.S. and Canadian cities. While these studies found some evidence of association between ozone and mortality, the relative strength and consistency for the underlying relationship varied. The available studies, taken together, were judged to provide sufficient support for a potential relationship to warrant inclusion in an upper bound estimate for the benefits analyses. Because benefit functions from one of these studies (Moolgovkar et al., 1995) were readily available without further analyses, the staff chose to use those functions to derive an estimate for use in the upper bound of the range of benefit estimates.

Ozone mortality is an instance where there are reasonable probabilities that the effect is nonexistent or that the effect could be significant. In this case, we believe it would be premature to set an air quality standard based on this evidence, but we also believe that an RIA estimate of benefits should reflect an "expected value" together with a range of possible outcomes. Therefore, for the RIA that is to be issued in July with the final NAAQS decisions, we are exploring statistical methodologies to evaluate all known studies that examined this effect (about a dozen), most of which have appeared since the closure of the ozone Criteria Document, to calculate the "expected value" and range of possible outcomes.

Question 12. Would the proposed ozone standard eliminate all of the premature deaths that might be expected to be caused by exposure to ozone in the ambient outdoor air?

Answer. As noted in answer to Question 11 above, EPA's assessment of the scientific evidence does not provide a basis to link a specific number of ozone-related premature deaths to a specific level of an ozone standard.

Question 13. Would the proposed ozone standard eliminate all of the adverse health effects that would be caused by exposure to ozone in the ambient outdoor air?

Answer. Attainment of the proposed ozone standard would not guarantee elimination of all adverse health effects associated with ambient ozone exposure for all individuals in the population. In the absence of a discernible threshold, it is not possible to select a level below which absolutely no effects are likely to occur. As discussed in response to Question 14, however, not all biological responses are adverse health effects. Moreover, legislative history of the Clean Air Act, past EPA decisions on NAAQS, and judicial decisions have made it clear that the primary standards are intended to protect the most sensitive population groups as a whole and not necessarily the most sensitive or most exposed individual. As discussed in the proposal notice (61 FR 65727), the Administrator's task becomes one of attempting to select a standard level that will reduce risks sufficiently to protect public health with an adequate margin of safety, since setting a zero-risk standard is neither possible nor required by the Act.

Question 14. If premature deaths or other adverse health effects would be caused by exposure to ozone at ambient levels below the standard you have proposed, how does the standard provide a margin of safety?

Answer. As noted in answer to Question 11 above, EPA's assessment of the scientific evidence does not provide any basis to suggest a significant risk of premature mortality in areas meeting the proposed ozone standard. With respect to other health effects of ozone, a key question is what constitutes an adverse effect. Some biological responses vary in degree, depending on the magnitude of exposure or other factors. Determining at what point such effects become so significant that they should be regarded as adverse within the meaning of the Act is a matter of informed judgment that must be exercised by the Administrator. To help inform such judgments, EPA seeks the advice and recommendations of the CASAC as well as other medical experts.

As discussed above in answer to Question 8, NAAQS are set at a level which provides an adequate margin of safety to protect against pollution levels that may pose an unacceptable risk of harm. In making such determinations, EPA recognizes that none of the options would provide a risk-free standard. For example, in establishing

the lead NAAQS in 1978, EPA clearly indicated that the standard level was based on preventing "most children" in the United States from exceeding the target blood lead level (43 FR 46246, October 5, 1978). In considering what standard level will provide an adequate margin of safety, the Administrator takes into account such factors as the nature and severity of the effect, the size of the sensitive population, and the likelihood and magnitude of exposure and associated health risk. In the case of ozone, estimates of the extent to which ambient ozone exposures cause effects below 0.08 ppm are based either (1) on extrapolation of exposure-response relationships to levels below those tested for lung function and respiratory symptom responses or (2) on observations of associations in community epidemiology or field studies, where exposure to ozone occurs with other pollutants and is not as precisely known. As a result, in contrast to the health effects clearly shown in controlled human exposure studies at levels down to 0.08 ppm ozone, there is increasing uncertainty about the number of individuals affected and the magnitude of the effects at levels below 0.08 ppm.

Based on the record at the time of proposal and the considerations discussed above, it was the Administrator's view that the proposed standard was requisite to protect public health with an adequate margin of safety. The Administrator also recognized at the time of proposal that there was a diversity of views on the significance of the various health effects associated with ozone exposure and the selection of an appropriate policy response in the face of scientific uncertainties. Accordingly, in the proposal notice, the Agency solicited comment on alternative 8-hour standards both more stringent and less stringent than the proposed 8-hour standard. In reaching a final decision on the ozone standards, the Administrator will have to decide, after a careful review of the public comments, what ozone standard will protect public health with an adequate margin of safety.

PREPARED STATEMENT OF SALLY KATZEN, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

Mr. Chairman, members of this committee, I am pleased to be here today to discuss EPA's recent proposals revising the ozone and particulate matter (PM) ambient air quality standards (NAAQS). These EPA proposals have sparked extraordinary interest from a wide variety of affected groups—environmentalists and health professionals, who view these standards as a necessary and important step to improving air quality; State and local governments, who have the front-line responsibility for implementing these standards; and industry and other entities, who will have to take the steps necessary so that areas comply with the proposed standards. The interests and concerns that have been expressed range from the health effects to be ameliorated by these standards—and the scientific support and other science policy issues underlying these standards—to the administrative and other practical means by which these standards will be implemented, to the economic effects of complying with these standards—the costs incurred by those who will have to change their conduct to implement these standards.

At least in my experience as Administrator of OMB's Office of Information and Regulatory Affairs (OIRA), there is more public interest in these two proposals than in any other recent rulemakings. And I am acutely aware of the interest and questions that have been raised about OMB's review of these proposed rules—from the simple logistics of how and when we did the review, to the substance of what we thought of the proposed rules and the accompanying regulatory analyses that EPA prepared.

The EPA Administrator has prepared extensive testimony, describing in detail the Agency's basis for the proposed environmental standards. The regulatory agency has the statutory authority and bears the responsibility for developing substantive regulatory standards. Executive Order No. 12866 specifically recognizes the primacy of Federal agencies in the regulatory decisionmaking process.

OIRA's role under the Executive Order is to provide dispassionate, objective review of the Agency's work. Our task is to assure that the regulatory agency asks the right questions, considers the relevant scientific and other data, employs sound analysis, and balances the competing concerns in a reasonable, practical way. In addition, for proposed rules, it is important that the regulatory agency presents its proposal, and the justification for it, in a way that assures informed, meaningful input from the public.

E.O. 12866 sets forth a number of principles generally applicable to regulatory decisionmaking. It was, however, purposefully qualified to apply "to the extent permitted by law." That qualification is particularly important in this case. Under the Clean Air Act (CAA), the EPA Administrator is to set air quality standards that

“protect public health with an adequate margin of safety.” Indeed, the EPA Administrator is not to consider economic factors in determining the appropriate standards.

Having said this, E.O. 12866 nonetheless requires agencies to prepare economic analyses for proposed and final rules and to submit them to OIRA for review, even if economic considerations cannot be a determining factor—or even a secondary or tertiary factor—in formulating the proposal. Where a statute prohibits the consideration of economic factors, such analysis is still important because it helps to inform the Administration, Congress, and the public of the benefits and costs of regulatory actions.

In fact, EPA prepared extensive benefit-cost analyses—over three inches of material—for these proposed standards. These analyses are based on ambitious and sophisticated modeling efforts using inventories of known emissions sources in which the Agency attempted to identify, locality by locality, the most efficient set of control measures for attaining the standards, the costs of these measures, and the extent of air quality benefits that would be achieved. Projected air quality improvements served as the basis for an assessment of potential health benefits, which were monetized by assigning dollar values to each health outcome.

It was particularly important that EPA prepared these economic analyses for these standards. While the standards themselves are health-based, and may not reflect economic considerations, they are not self-executing. Instead, EPA must follow-up these standards with regulations to implement them. In the ordinary course, this would include: specifying how one would determine whether localities are, or are not, in attainment; the timing for achieving attainment; guidance on control strategies to achieve attainment; etc. In this implementation phase, costs should and will play a very significant role. Preparing the benefit-cost analyses during the standard-setting phase will ensure that those addressing the implementation issues—EPA, its advisory committees, the State and local governments who are responsible for implementing these standards, and all those affected by the standards—have the best information available.

Let me now discuss briefly the specifics of OMB’s review of these proposed standards. Before we received the proposed rules, OIRA staff had attended a number of meetings at which EPA explained in general terms the methodology it was using in its analysis of these rules (e.g., data, assumptions, models, etc.). In addition, EPA and OIRA staff had hosted a number of interagency meetings with EPA staff briefing other Federal agencies on the general issues surrounding EPA’s review of ozone and particulate matter standards.

EPA submitted the proposed rules on November 4, 1996. We had to work quickly because of a court-ordered deadline to issue the particulate matter standard by November 29, 1996. Although there was no court-ordered deadline for the ozone standard, EPA thought it important to publish the two proposals simultaneously. This would allow the regulated community and other interested entities to evaluate each of the proposals with the other in mind, and to consider how the two proposals would interact.

During these 3 weeks available for review, my staff worked intensively, often late into the evenings and weekends. We gave this matter top priority, putting aside or postponing other responsibilities. We were able to identify a number of issues that require further work, and while the court-ordered deadline precluded full discussion and resolution of these issues with EPA, we have been advised by EPA that some of these issues will be analyzed as part of the economic analyses that will be provided to us as part of the package for our review of the final standards.

At the final rule stage, we will fulfill our obligations for review of these rules under the Executive Order. There are important policy issues that need to be considered. And, as at the proposed stage, we expect that many affected parties will want to meet with us and share their views to assure that we give careful consideration to the relevant issues.

Thank you for the opportunity to comment. I welcome any questions.

RESPONSES BY SALLY KATZEN TO ADDITIONAL QUESTIONS FROM SENATOR INHOFE

Question 1. I understand the OMB review process for the proposed regulations was very short this fall, approximately 3 weeks. How long do you normally spend on such a review, and what steps did you shorten during your review? Where there any documents that you didn’t have time to study and review during the process?

Answer. Under Executive Order 12866, OIRA generally has up to 90 days for its review of proposed rules; our most recent statistics indicate that the average time for review is roughly 45 days. With respect to these proposed rules, as I indicated

in my testimony, even before receiving the proposed rules, OIRA staff had attended a number of meetings at which EPA explained in general terms the methodology it was using in its analyses of these rules. Once we received these draft proposals, OIRA staff worked intensively, often late into the evenings and on weekends. We gave this matter top priority, putting aside or postponing other responsibilities.

As a result of this review, we were able to identify a number of issues that required further work. While the court-ordered deadline precluded full analysis of these issues with EPA, we have been advised that these issues will be analyzed as part of the package for our review of the final standards.

Question 2. How much time will you need to adequately review the final rule, given that this is perhaps the largest environmental regulation ever?

Answer. As noted in response to the previous question, we have essentially continued our review of these rulemakings since the publication of the proposed standard, and have already begun to focus on the final rule packages. Given that these are very significant environmental regulations—highly visible and controversial—and that the court has been unwilling to grant an extension of time, we are prepared to devote all available resources in the time allotted.

Question 3. Did you have enough time to adequately perform a cost/benefit analysis? Did you follow the Clinton Executive Order for Cost Benefit Analysis for Major Rulemakings?

Answer. Under Executive Order 12866, it is the Agency that has the responsibility to provide an assessment of benefits and costs of economically significant rules (see section 6(a)(3)(C)), and it is OIRA that has the responsibility to provide meaningful oversight so that the Agency's regulatory action is consistent with applicable law, the President's priorities, and the regulatory principles set forth in the Executive Order (see section 6(b)). The "Cost Benefit Analysis" document referred to in your question is not an Executive Order but rather what we characterize as a "best practices" document, entitled "Economic Analysis of Federal Regulation under Executive Order 12866," that was prepared by an interagency group and released by OMB on January 11, 1996.

In a letter dated December 16, 1996, the Honorable Thomas J. Bliley, Jr., Chairman, House Committee of Commerce, asked our views of whether, and to what extent, EPA's economic analyses followed the significant technical requirements for economic analysis set forth in the "best practices" document. I have attached a copy of my January 15, 1997, response to the chairman. The relevant material is at pages 4 to 6.

Question 4. How do you know the potential impacts without knowing which counties might be in noncompliance? What potential difficulties are there in analyzing impacts without monitoring data available? Was there additional data that would have made your review more productive?

Answer. EPA projected the number of non-attainment areas using existing data on particulate matter levels for particles that are less than 10 microns in size (PM_{10}) in counties across the Nation and estimates of particulate matter levels for particles that are less than 2.5 microns in size ($PM_{2.5}$) that typically comprise a given level of PM_{10} . As a part of our review, we requested that EPA present the extent of the uncertainty of its estimates. In the absence of better data on $PM_{2.5}$ levels in these counties, EPA's analysis of the extent of noncompliance will necessarily be limited to the analysis in the current Economic Analyses.

Question 5. Are there scientific uncertainties involved with these proposals? Does your office believe more data or research might be warranted?

Answer. As I pointed out in my January 15, 1997, response to Chairman Bliley, EPA frankly acknowledged that there is substantial scientific uncertainty in the risk analyses on which the benefits are based. For my discussion of this issue, see page 6 of the attachments.

As a general matter, the amount of research data should be commensurate with the significance of the decision. Given the sweeping scope of these two proposed standards, more data or research would most likely be useful, particularly for the particulate matter standard. On the other hand, it should be recognized that, depending on the risks, social policies, and equity concerns involved, an agency has the responsibility to decide, despite uncertainties, what sound public policy requires to be done now.

RESPONSES BY SALLY KATZEN TO ADDITIONAL QUESTIONS FROM SENATOR BOXER

Question 1. What about all of the effects that cannot be monitored? How do you ensure that they are not ignored in the evaluation process?

Answer. In Executive Order 12866, President Clinton set forth the regulatory philosophy and principles of regulation that he wanted his Administration to follow in developing its regulations. He stated:

In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. (Sec 1(a)). (Emphasis added.)

The President placed the responsibility for taking these principles into consideration not only on the rulemaking agencies, but also on the Office of Information and Regulatory Affairs (OIRA) in OMB. In our "best practices" document for performing economic analyses, we reiterated the importance of including in economic analyses both those benefits that can be readily quantified, as well as those that are difficult to quantify and should be assessed in a qualitative manner.

Question 2. How does OMB take into account the "cost of delay?" Suppose we waited three more years to revise the standard—the best scientific estimate seems to be that 60,000 additional lives would be lost. Isn't that a powerful argument for making a decision soon?

Answer. As a general matter, if an agency has reasonable confidence that a rulemaking would improve the health or safety of the American public, and if the rule otherwise satisfies applicable legal and policy standards, then the agency should move promptly to complete the rulemaking and begin to realize the intended benefits. Given the assumption posited in your question, there would be considerable benefits associated with earlier implementation of the standard.

LETTER SUBMITTED FOR THE RECORD BY OMB

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, DC, January 15, 1997.

The Honorable THOMAS J. BLILEY, JR.
Chairman, Committee on Commerce
U.S. House of Representatives

DEAR MR. CHAIRMAN: This is in response to your letter of December 16, 1996, regarding the Office of Information and Regulatory Affairs' (OIRA) review of the Environmental Protection Agency's (EPA) recently proposed revisions of the National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter.

You asked for my response to four specific questions.

Question 1. According to section 6(b)(2)(B) of the Executive Order, the Office of Information and Regulatory Affairs (OIRA) is supposed to have up to 90 days to review "significant regulatory actions." This period of time is generally believed to be necessary to analyze complex draft regulations. Yet, it appears that OIRA had only about 3 weeks to review these very important rules despite advance knowledge of a judicial deadline of November 29, 1996 for Agency action.

Question 1a. Please explain why these draft proposed regulations were not submitted to OIRA at a substantially earlier date in order to provide OIRA with a 90-day review period as contemplated in the Executive Order.

Answer. Questions about the timing of EPA's submission of the proposed rules to OIRA can best be responded to by EPA.

Question 1b. Please explain what efforts you made to ensure the submission of these proposed rules to OMB in time for a normal regulatory review as envisioned in the Executive Order.

Answer. We originally expected EPA to submit the proposals in early September. As it became apparent that submittal of the proposals would slip, I made a number of requests to EPA to submit these proposals as soon as possible so as to provide OMB and other Federal agencies with time to properly review them.

Question 1c. Given the short amount of time available to OIRA for review prior to the judicial deadline, please explain the extent to which OIRA was kept informed by EPA prior to formal submission of the various draft rules for OMB review, particularly with respect to (i) data, assumptions, models and analytic methods which were to be the foundation of the regulatory analysis; and (ii) the alternative standards under consideration.

Answer. A number of meetings were held over an extended period of time with EPA explaining in general terms the methodology it was using in its analysis of these two rules (e.g., data, assumptions, models, etc.). In addition, EPA and OIRA staff hosted a number of interagency meetings with EPA staff briefing other Federal agencies on the general issues surrounding EPA's review of the ozone and particulate matter NAAQS.

Question 1d. The presence of an inflexible judicial deadline appears to have substantially curtailed OIRA's review of these important rules. Please explain whether, and to what extent, you believe that the judicial deadline adversely affected OIRA's ability to perform its regulatory review responsibilities under the Executive Order.

Answer. During our discussions with EPA staff before the Agency submitted the proposals, we identified a number of issues that were not resolved in the draft proposals submitted to OMB for review in early November. The abbreviated period of review required an intensified effort on our part and on the part of other agencies and EPA, and several issues were not able to be fully analyzed prior to publication of the proposals. We have been advised by EPA that these issues will be analyzed as a part of the Economic Analyses for the final rules.

Question 2. Section 1(b) of the Executive Order sets forth a number of analytic and decisionmaking principles that the Administration uses to guide regulatory decisionmaking. Please explain the extent to which, in your view, these proposed regulations satisfied each of the principles set forth in this subsection of the Executive Order.

Answer. Executive Order No. 12866 establishes 12 general Principles of Regulation that agencies should follow. (See the attached list of principles from the Executive Order.) A discussion of these principles as they apply to these proposals follows. We note that EPA will be preparing final Economic Analyses in response to comments on the proposals from the public and from other Federal agencies. These final Analyses will be available for Congress to refer to during its review process after promulgation of the standards.

(Nos. 1, 2, 12) EPA clearly identified the problem that it intends to address and the significance of this problem. Ozone and particulate matter air pollution is a problem of "market failure. Private markets fail to achieve optimal levels of pollution control because the benefits of pollution control do not primarily accrue to those who must pay the costs to control pollution. This classic economic problem of "externalities" is described clearly in the Economic Analysis. This problem is not caused by existing regulations. EPA clearly defined and described the proposed standards.

(Nos. 1, 4, 7) The Clean Air Act (CAA) requires EPA to review NAAQS every 5 years to ensure that they are protective of human health and the environment. As part of this process, EPA has completed comprehensive assessments of the peer-reviewed scientific literature on the public health and welfare (e.g., visibility and vegetation damage) effects of concern associated with these pollutants. These assessments were reviewed by the Clean Air Scientific Advisory Committee (CASAC), an independent review panel established by statute, with an opportunity for public comment during the Committee's review. While CASAC was concerned about scientific uncertainties that exist with regard to these effects and the lack of adequate research on fine particles, it concluded that EPA's assessments provide an adequate scientific basis for the Administrator to make policy decisions regarding revisions to the existing standards.

(No. 3, 5, 8, 11) NAAQS are set to protect public health with an adequate margin of safety and to protect public welfare from the adverse effects of the pollutants of concern. Under the law, EPA is not allowed to consider costs and other economic factors in setting health-based NAAQS. EPA and OMB are, of course, very concerned about the economic impacts of meeting any new standards and agree that Congress and the public should be fully informed as to the estimated costs and benefits that may result from their implementation. EPA's Economic Analyses were prepared under Executive Order No. 12866 in order to inform the public about the expected benefits and costs of these standards as well as to guide implementation efforts to attain these standards in a cost-effective manner.

EPA has not proposed any specific compliance strategy or a specific set of control measures for complying with the new standards at this time; instead, it has indicated that it intends to propose an implementation strategy at a later date that incorporates recommendations from a subcommittee of the Clean Air Act Advisory Committee. The specific purpose of this subcommittee is to advise EPA on ways to develop innovative, flexible, practical, and cost-effective implementation standards to attain the proposed standard. Regarding distributional impacts, EPA has tailored the proposed standards to provide additional protection for sensitive subpopulations

(e.g., outdoor exercising children, asthmatics, and the elderly). The analyses for these proposals did not address the distributional and equity effects of the rule.

(No. 9) EPA states in the preambles to both rules that the proposed revisions to the standards “will not in themselves impose any new expenditures on [state and local] governments” and thus EPA has not performed any analysis of effects on such governments. EPA recognizes that any corresponding revisions to associated State Implementation Plan requirements and air quality surveillance requirements may require additional expenditures. EPA has advised us that these effects will be addressed at the time such revisions are proposed and consultations with State and local governments will be conducted at that time.

(No. 6, 10) EPA has found it difficult to assess fully the costs and benefits of the proposed rules. Application of all known control measures would be insufficient to achieve compliance with the current ozone NAAQS in four metropolitan areas, and in 50 counties for the current PM NAAQS. The number of such “residual nonattainment areas” would increase significantly under the proposed standards. The cost estimates EPA presents in its Economic Analyses represent this “partial attainment” scenario based on currently identified measures with known costs that EPA considers likely to be implemented. EPA believes that new, cost-effective measures for reducing emissions of fine particles, NO_x, and VOCs will be developed in the future and will ultimately allow the residual nonattainment areas to come into compliance, but it has not estimated the costs of these as yet unknown measures. EPA also calculated benefits for the partial attainment scenario and found monetized benefits to be greater than costs for the proposed PM standard and less than costs for the proposed ozone standard.

There is also a potential overlap between control strategies to address ozone and particulates. For this reason, EPA intends to combine the implementation of the two standards to allow for efficient measures to reduce both particulates and ozone precursors simultaneously. However, EPA has not analyzed the extent to which the adoption of one of the two standards might reduce the benefits and costs of the other standard.

Question 3. Section 6(a)(3)(C) of the Executive Order sets forth certain requirements for the analysis of costs and benefits of “significant regulatory actions.” On January 11, 1996, OMB published a guidance document entitled “Economic Analysis of Regulations Under Executive Order 12866,” to guide agencies’ fulfillment of these analytic requirements. This document describes the elements that agencies should include and the economic methods and practices that agencies should use in performing economic analyses under the Executive Order.

(a) Please explain whether, and to what extent, EPA’s economic analysis meets or fails to meet each of the significant technical requirements for economic analysis set forth in OMB’s guidance document, entitled “Economic Analysis of Federal Regulations Under Executive Order 12866.”

(b) Please identify any and all technical errors in EPA’s economic analysis discovered during OIRA’s review which had, or may yet have, a material effect on the public’s complete and clear understanding of the risks, costs, and benefits of these proposed rules.

Answer. The “Economic Analysis of Federal Regulations Under Executive Order No 12866” lists three basic components of the prepublication “Best Practices” analysis of Federal regulations: a statement of need for the proposed action, an examination of alternative approaches, and an analysis of benefits and costs. The document includes a number of general principles and technical suggestions for each of these components; it is not intended to serve as a formulaic checklist.

Statement of need for the proposed action

The Best Practices document suggests two general topics that should be discussed: the market failure, if any, that the regulation is designed to correct, and the appropriateness of solutions other than Federal regulation, such as market mechanisms or state and local regulation. As discussed in response to question 2 above, EPA provided a discussion of the market failure which gives rise to the need for air quality standards. The CAA mandates Federal standards to address this problem and sets specific health-based criteria for standard-setting.

Examination of alternative approaches

The Best Practices document lists several different types of alternatives which should be considered where appropriate, including performance oriented standards, alternative levels of stringency, alternative effective dates of compliance, and informational measures.

Air quality standards are by their very nature performance standards. The Economic Analyses considered several different levels of stringency for both the ozone

and PM proposals, but they did not evaluate some of the other types of alternatives listed above. For example, the current proposals do not include implementation schedules for attainment of the new standards OMB has been advised that this issue will be addressed at the implementation stage. Finally, in the ozone proposal, EPA discussed the communication of public health information as a complement to the NAAQS, but did not consider or evaluate such an approach as an alternative to progressively more stringent NAAQS.

Analysis of benefits and costs

The Agency conducted extensive analyses of the costs and benefits of the proposed standards. These included sophisticated modeling efforts based on inventories of known emissions sources in which the Agency attempted to identify, locality by locality, the most efficient set of control measures to attain the standards, the costs of these measures, and the resulting air quality improvements. These projected improvements then served as the basis for an assessment of potential health benefits, which were monetized by assigning dollar values to each health outcome. While these analyses were consistent with the Best Practices document and produced much useful information, there were several areas where additional work would have been productive; EPA has advised us that these areas, noted below, will be addressed in the Economic Analyses accompanying the final rules.

EPA's analytic baseline is compliance with the current NAAQS in 2007. For the ozone NAAQS, EPA did not disaggregate the cost of the control measures to meet the baseline. For the particulate standard, the 2007 baseline control measures and the associated costs were not presented. Finally, neither standard included adoption of the other in its baseline, which could result in an overstatement of benefits and costs of both rules.

EPA evaluated several alternative standards of differing stringency in its analysis of both NAAQS. In its ozone analysis, however, EPA presented an analysis of two options that "bracket" its proposed option, but not the proposed option itself. EPA prepared no quantitative analysis of the projected costs and benefits of its proposed "SUM06" secondary standard.

EPA frankly acknowledged that there is substantial scientific uncertainty in the risk analyses on which the benefits estimates are based. However, the analyses did not fully reflect the ranges of uncertainties associated with various assumptions and ad hoc adjustments in the models. In the case of fine particles, for example, the uncertainty attributable to the lack of an identified biological mechanism for the health effects of concern and the possibility of a threshold concentration below which there are no adverse effects were not reflected in the range of estimated benefits. For analyses as complex as these, it is difficult to document fully all assumptions. Nevertheless, there are several areas where additional clarification and sensitivity analyses would be helpful. For example, a large share of the estimated benefits are due to—and sensitive to—assumptions about improvements in air quality during off-peak periods, the periods in which most cumulative low-level exposure occurs. For the ozone standard, the basis of this "rollback" assumption is not clear, nor has the Agency performed a sensitivity analysis, as it did for the particulate matter rollback assumptions.

As suggested in the Best Practices document, the analyses discussed several categories of benefits that have not been quantified or monetized. These include prevention of various respiratory symptoms; benefits to ecosystems, including plants and sensitive water bodies; prevention of materials damage and visibility improvements. In addition to monetized costs, there were also costs that have not been monetized. These include the administrative costs to states and local governments to plan and implement air quality programs. Finally, the analyses were presented in terms of annual benefits and costs, and neither costs nor benefits are discounted.

Question 4. According to press accounts summarizing EPA's recent announcements, the proposed new standards will result in costs to society of approximately \$6.5 to \$8.5 billion per year and annual benefits to society of \$120 billion. Others have suggested that these figures may not be reliable. Based on OIRA's independent and objective analysis, please provide OIRA's best professional estimate of the expected costs and benefits of each of these proposed regulations presuming that each is fully implemented as proposed.

Answer. OIRA has not prepared its own estimate of the likely benefits and costs of attaining these proposals. We note, however, the following. As to costs, the estimate of approximately \$6 to \$8.5 billion per year is a combined estimate for both the ozone and particulate matter NAAQS EPA estimated costs of \$0.6 billion to \$2.5 billion per year for the proposed ozone NAAQS and \$6 billion per year for the proposed particulate matter NAAQS. Each of these estimates is for partial attainment. EPA did not estimate the costs of full attainment because it is not possible to esti-

mate the costs of the as yet unknown measures that will be required to allow residual nonattainment areas to come into compliance.

As to benefits, the estimate of the benefits to society of \$120 billion per year is a combined estimate for both the ozone and particulate matter NAAQS. EPA estimated benefits for partial attainment of the ozone NAAQS of approximately \$30 million per year, with a range from \$10 million to \$1,200 million per year, and it estimated benefits for partial attainment of the particulate matter NAAQS of \$60 billion to \$120 billion per year.

As reported in the Economic Analyses for the proposals, there are a variety of ways in which these estimates may overstate or understate the benefits and costs of these proposals, including factoring in nonquantifiable costs and benefits, uncertainties, and efficiencies.

Sincerely,

SALLY KATZEN,
Administrator.

ATTACHMENT

PRINCIPLES OF REGULATION

EXECUTIVE ORDER NO. 12866

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regu-

latory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

STATEMENT OF THE PETROLEUM MARKETERS ASSOCIATION OF AMERICA AND THE
INDEPENDENT OIL MARKETERS ASSOCIATION OF NEW ENGLAND

My name is Joseph Tomaino. I am President of the Independent Oil Marketers Association of New England (IOMA) and I am testifying for both that Association and the Petroleum Marketers Association of America. These Associations represent almost 10,000 independent petroleum marketers. Nearly 90 percent of these marketers are small businesses and it is on their behalf that I offer my testimony.

We are opposed to the EPA proposal to alter the Ozone and Particulate Matter Air Quality Standards.

EPA is moving quickly down the path to the holy grail of many a regulatory rule writer: the unreachable standard. The billions spent by business, industry and consumers to meet the requirements of the 1990 amendments to the Clean Air Act have been successful. They have been so successful that the environmental bureaucracy appears to be in a frenzy to move the goal posts before the public can recognize the absurdity of an added wave of Draconian transportation controls and restrictions on industrial expansion. The lowering of these standards will have a profound effect on the small businesses that we represent as well as other businesses and consumers throughout the country. These proposals will stymie the growth that is so essential to our national economy and America's workers.

First, we are concerned that the establishment of the proposed standard is only marginally linked to public health. Second, we believe that EPA has not allowed sufficient time for comment on this proposal and has denied small business the opportunities afforded by the Small Business Regulatory Flexibility Act to fully participate in the preparation of the proposal. Third, EPA has not measured the likely costs of this proposal and their impact on the economy.

The same group of scientific advisors that EPA is relying upon as the basis for its severe ozone restriction has acknowledged that "there is no 'bright line' which distinguishes any of the proposed ozone standards * * * as being significantly more protective of public health". More importantly they have highlighted the rush to judgment nature of EPA's proposal by conceding at "there are still many gaps in our knowledge and large uncertainties in many of the assessments".

The scientific case for a change in the particulate matter standard is equally shaky. Recently, the highly respected Health Effects Institute of Cambridge (directed by former MA DEP Commissioner, Daniel Greenbaum) questioned (through a team of scientists at John Hopkins University) the proposed particulate standard change on the grounds that EPA has failed to establish an unambiguous scientific basis for its health effect claims linked directly to particulates. Add to this the fact that the Harvard School of Public Health, the principle source of data for EPA's decision to further restrict particulate matter, *has steadfastly refused to disclose lost of the raw data for its conclusions in the six cities study to the general scientific community*. Even though several of the studies in question were commissioned by EPA, the Federal agency claims it is helpless to force Harvard to share its raw data. Recently, we hear that HSPH, perhaps as a result of pressure from the scientific community, is "negotiating" with the Health Effects Institute to turn over more raw data later this month or perhaps in February. As we all now, the deadline for comment on these proposals is February 18th.

The small business community is forced to assume that EPA, who paid for this research with public money and now relies upon these studies to justify its particulates proposal, has tacitly permitted, if not encouraged, Harvard to withhold its raw data from full scientific peer review.

In May, 1994 the Clean Air Scientific Advisory Committee asked EPA to take the lead in requesting that the particulate researchers make available the "primary data sets" so that a broad spectrum of researchers could validate the analysis. Apparently, this 1994 request, by the agency's own scientific advisory committee, fell on deaf ears.

This proposal has been referred to as the biggest air quality restrictions ever proposed by EPA. will lead to the reclassification of many cities into non-attainment that were not classified as such by Congress during their 1990 deliberations on the Clean Air Act. During consideration of Clean Air Act, Congress and the President established a multi-tier system for classifying cities as to their non-attainment sta-

tus for ozone and established appropriate control measures. This proposal would dramatically alter the way control measures are established and applied.

Allowing interested parties a mere 60 days to comment on such a sweeping proposal is unconscionable. EPA argues that the appearance of haste is due to the fact that they are proceeding under court order. However, EPA's media messages generally neglect to point out that the Federal court order does not in any way involve the ozone standard.

Congress clearly anticipated that the EPA would provide sufficient time for small business to comment and work with the agency on proposals that would affect their business. Separating a proposal that will lead to a requirement that states and locals impose control measures on industry under Federal law and then claiming such a proposal does not impose costs on industry is at best a mythical separation.

Some analysts have estimated that the proposed new standards would result in over 800 non-attainment areas triggering automatic environmental controls. Non-attainment classification would require state and local governments to impose additional pollution control measures.

Independent petroleum marketing companies have already expended tremendous resources to stall vapor recovery systems and distribute reformulated gasoline and multiple types of diesel fuel. The cost of compliance with the additional Federal and state controls made necessary by this proposal's lower standards will have a devastating impact on these independent motor fuel marketers. We can anticipate a further reformulation of gasoline and diesel fuel, an expansion of fuel programs to off road use vehicles and engines and additional requirements for vapor recovery at retail outlets. The result will be increased refining and marketing costs that must be passed on to consumers and businesses.

Based upon the shaky scientific foundation for the proposal, insufficient time provided for comment and input and the astronomical implementation costs we urge EPA to reaffirm the existing standards for ozone and particulate matter. At the very least, the agency should not rush a conclusion. The ozone issue is not subject to court order and therefore need not be rushed. While the particulate matter standard is subject to court order, the agency should simply petition the court for additional time.

Thank you for this opportunity to testify.

CLEAN AIR ACT: OZONE AND PARTICULATE MATTER STANDARDS

MONDAY, MARCH 3, 1997

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON CLEAN AIR, WETLANDS, PRIVATE
PROPERTY AND NUCLEAR SAFETY,
Oklahoma City, OK

STATE IMPLEMENTATION ISSUES

The subcommittee met, pursuant to notice, at 11 a.m. at Oklahoma City Community College, 777 South May Road, Oklahoma City, OK, Hon. James M. Inhofe (chairman of the subcommittee) presiding.

Present: Senators Inhofe, Hutchinson, and Sessions.

Also present: Senator Thomas.

OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator INHOFE. The meeting will now come to order.

Before we start welcoming our panelists we'll make a few comments.

I'd first like to thank the Oklahoma City Community College for generously letting us use your resources here. This is a great facility. It's close and convenient to the Will Rogers Airport. And I think now that we'd all agree it's one of the finest institutions around. We're very, very proud of being—we thank you very much for allowing us to be here.

Let me welcome everyone to today's subcommittee hearing, certainly welcome Governor Hollister and Governor Keating. I would like to introduce my colleagues: Craig Thomas, is the U.S. Senator from Wyoming; Tim Hutchinson is the U.S. Senator, our neighbor over here to the East from Arkansas; Senator Jeff Sessions is from Alabama. I appreciate very much all of you coming along with all of the witnesses.

Today the subcommittee is holding its third hearing on this subject. The name of this subcommittee is the Subcommittee On Clean Air, Property Rights, Wetlands and Nuclear Safety. It's a subcommittee of the Environment and the Public Works Committee, I'm the chairman of this subcommittee.

This is the third hearing we've had concerning the EPA's proposed changes in the National Ambient Air Quality Standards for ozone and particulate matter.

The purpose of this hearing today is to hear from State and local governments to determine how they would be affected.

Last December, we found out about these proposed changes by the Administration, this actually happened right during the Thanksgiving holidays, and some of it went unnoticed.

I went around the State of Oklahoma and convened 21 meetings in 21 counties. We felt that they might have to go out of attainment if this were to be passed, so we had a chance to talk to a number of people at that time. Now we've progressed and the comment period has been delayed a little bit and we're into it hot and heavy.

I believe it's important to ensure that everyone, here in Oklahoma and around the country, has clean air to breathe. The one thing that we all agree, every witness that's going to be here today and all of those in the room, is that we do want clean air.

I think the changes in our national clean air policy must be carefully considered regarding science and the impact it will have on our citizens.

Our first hearing was the scientific hearing. We invited some of the members of CASAC—the Clean Air Science Advisory Committee, which is a committee set up by statute to make recommendations to the EPA as to the science behind proposed changes and regulations. There are 21 scientists. We had our first hearing from these scientists. Some were for and some were against it, but the one thing that they all agreed on is that this is premature, that there is no scientific justification for making changes today and to relate certain PM standards or PM types as to affecting respiratory illnesses.

The one thing they all agreed unanimously on is that they needed at least 5 more years before they can make a determination that these standards should be adopted.

At the second hearing we heard from Carol Browner, the Administrator of the EPA. She defended her proposals even to the point of contradicting her own science experts. Since that hearing we have discovered the EPA has even tried to censor other Federal agencies that disagree with them, specifically the President's own Office of Management and Budget.

Congressman Tom Bliley from the State of Virginia discovered a memo from the EPA to the OMB instructing them to remove language from their analysis that contradicted what the EPA believes.

Specifically, the EPA wrote the OMB, "As written, the OMB's response could very well damage—be damaging to the PM and ozone National Ambient Air Quality Standards effort. Thus, we strongly recommend that OMB employ language much more similar to language previously submitted by the EPA to the OMB."

Now, I have to state to the witnesses here and those in attendance, this is the first time that I can recall any agency that's proposing changes in standards to try to influence a report out of the OMB.

We're going to address this when we get back to Washington, but for today's purposes I think you should be aware of it.

Today's hearing is to talk to people in the community, people in the State as to how they would be affected under this proposed—

the two proposed rule changes in both particulate matter and ozone standards.

Besides the obvious effect on local communities, States, the proposed regulations would have a direct impact because the States and local governments will be expected to implement the procedures.

I have been disturbed that Carol Browner, the Administrator of the EPA, has consistently made statements that—it's scare tactics when you talk about car pooling and about when you can barbecue and having inspectors come into the State and tell us what we can do. She claims that that's not going to happen.

She bases that claim on the fact that the States will be doing this. They will be responsible for doing it. We'll just be telling them what to do and, therefore, if they do that it's the States making those impositions.

I would suggest, however, that out in California where none of the communities, very few of the communities are in compliance they have done such things as mandated car pooling, has restricted the time of day that you can burn fires and cook on your patio. So, I don't think that's completely out of the realm of possibility even here in the State of Oklahoma and the other States that are here today.

The last thing I want to mention is we passed two laws last year, one that would stop unfunded mandates and the other was called the Small Business Regulatory Flexibility Act.

I can remember when I was mayor of Tulsa, I'm sure the mayors who are here today would agree with this, that the one thing that concerns us the most is unfunded mandates.

In other words, the Federal Government coming in, telling us things that we must do but not sending the funding. This is something that the Government's been good at, so we passed a law saying that you can't do that anymore.

Well, the EPA is contending that that doesn't apply. If there are mandates those mandates will come from the States and, therefore, it's not the Federal Government making that mandate.

They also say that in the Small Business Regulatory Flexibility Act, which was passed so that any change in regulation would have to determine what effects it has on small entities, it's called—small entities are defined as small businesses and individuals.

The EPA is contending that there are no effects on small business or on individuals because if there are changes then it will be the States who are responsible for that and not the Federal Government.

So, I think we have an impasse here in the way that we're interpreting the intent of the unfunded mandates law in the Small Business Regulatory Flexibility Act.

Last, I would say that we're going to have these major impacts, and we've had a chance to really spend some time and we have an excellent group of people here today to—as witnesses.

[The prepared statement of Senator Inhofe follows:]

PREPARED STATEMENT OF HON. JAMES INHOFE, U.S. SENATOR FROM THE
STATE OF OKLAHOMA

The hearing will now come to order.

I would like to welcome everyone to today's subcommittee hearing, particularly my colleagues Senator's Jeff Sessions of Alabama, Tim Hutchinson of Arkansas, and Craig Thomas of Wyoming. I would also like to thank in advance our witnesses today and welcome everyone to Oklahoma City.

Today's hearing is the third in a series of hearings examining the EPA's proposed changes to the National Ambient Air Quality Standards for ozone and particulate matter. The purpose of the hearing today is to receive testimony from State and local government officials on how the proposed changes would effect their States and communities. Last December, I traveled around Oklahoma conducting 21 meetings with different civic groups, Chambers of Commerce, and concerned citizens in areas which would be in nonattainment under the EPA proposals. I did this to alert everyone to these regulations and begin the process of obtaining feedback from the State. Today we continue that process by hearing from elected officials.

I believe it is important to ensure that everyone, here in Oklahoma and around the country, has clean air to breathe. But I think that changes to our national clean air policy must be carefully considered regarding the science behind the changes and the impacts on our citizens. These proposals to tighten the rules are coming at the same time that the EPA has reported that the quality of our air has been improving over the last 20 years. Our air is cleaner today than it was just 5 years ago. Is it right to tighten the rules even more, or should we continue to let the measures we have in place improve our air before we act?

Our first hearing, held in Washington, DC, examined the scientific issues behind the EPA's proposal. We heard from a balanced panel of scientific experts expressing a broad range of opinions. Probably the most important fact to come out of that hearing was a clear call for more time by the scientific community to study the issues behind the proposals. Even the most outspoken supporter of the Agency's proposal admitted that we need at least 5 more years before we can understand all of the issues in the proposal.

At the second hearing, we heard from Carol Browner, the Administrator of the EPA. She defended her proposals, even to the point of contradicting her own science experts. Since that hearing we have discovered that the EPA has even tried to censor other Federal Agencies that disagree with them, specifically the President's own Office of Management and Budget regarding the economic analysis required by law.

Congressman Bliley of Virginia discovered a memo from the EPA to OMB instructing them to remove language from their analysis that contradicted what the EPA believed. Specifically, EPA wrote to OMB, "As written, the OMB's response could be very damaging to the PM and Ozone NAAQS effort. Thus we strongly recommend that the OMB employ language much more similar to language previously submitted by the EPA to the OMB."

However, these discoveries have not stopped the rhetoric coming from her Office. But these are issues that my subcommittee will investigate further back in Washington, DC.

Today's hearing will concentrate on the effects these regulations would have on communities across the Nation if they are enacted as proposed. Oklahoma City was selected for this hearing because it is a community that has been in attainment under the current rules but would be thrown into nonattainment based upon its average ozone levels of .085 parts per million. The current rule is .12 parts per million and under the EPA's proposal, the level would be dropped to .08. Under the proposal, hundreds of counties across Oklahoma and the Nation would be in nonattainment for either ozone or PM, with many communities failing the standards for both.

Besides the obvious effect on local communities and States, these proposed regulations would have a direct impact because the States and local governments will be expected to implement procedures to reach attainment. States will be forced to rewrite their State Implementation Plans to account for the changes in the standards and local communities will need to adopt new strategies to control emissions. Carol Browner has been highly critical to claims that these regulations would outlaw barbecues and force car pooling. She swears that these proposals will not result in these controls. But what she fails to mention is that the actual implementation steps would be decided at the local level, and that communities in California have previously considered such limits. Now they may be forced to implement them because of the stricter controls. While I do not expect any of today's witnesses to explain how they would meet the new standards, I am extremely interested in whether they would be able to meet them, and what the standards would in essence require.

In addition, I hope the witnesses can address how these proposals would impact their resources and whether this is the best use for their resources. Besides the demands other programs place on your limited funds, are these issues even the most important environmental concerns facing your communities? Too often in Washing-

ton, every bureaucrat believes that the problem they work with requires the spending of unlimited funds and deserves priority over everything else.

I hold the position that these proposed regulations violate recently passed legislation. Specifically the Unfunded Mandates Law and the Small Business Regulatory Flexibility Act.

Carol Browner has stated that these regulations are not an unfunded mandate because the implemented steps will be required by the States, not the Federal Government. She also believes that the proposals will not impact small businesses, because the States will be the ones to impact the businesses, not her. So I would also like to hear if you, as Governors, Mayors, State Senators and Councilmen will have the flexibility not to impact State resources and small businesses, or will the EPA be requiring you to act. When I was the Mayor of Tulsa, I would have considered this to be another example of Federal intrusion into local matters. I am extremely interested in hearing what our witnesses have to say about these matters.

Senator INHOFE. What I would like to do is—we have plenty of time, I'm not going to try to adhere to a real tight time schedule, but let's say if you folks who are witnesses would submit your entire testimony in writing it will get into the record and we'll have the benefit of that, but you might hold your remarks down to 5 or 10 minutes if at all possible.

We'll time it at, what, 7½ minutes and that will give you an idea. But we're not pressed for time today so we'll go ahead and on with the show.

First of all, one of my close personal friends, the Honorable Frank Keating, Governor of the State of Oklahoma. My next door neighbor for years in Tulsa and someone I'm very proud to have as my Governor.

Governor Keating.

Governor KEATING. Thank you Senator Inhofe.

Mr. Chairman, and members of the subcommittee, we are obviously very honored to have you in Oklahoma to give you an opportunity to hear our concerns.

Senator INHOFE. Let me interrupt for just a minute, Governor Keating. I goofed, I should have asked for opening statements from the other Senators. So, just remember where you are and I'll come right back to it.

Governor KEATING. It's always easy to welcome people.

Senator INHOFE. Let's start off over here on the left side with Senator Thomas from Wyoming.

**OPENING STATEMENT OF HON. CRAIG THOMAS, U.S. SENATOR
FROM THE STATE OF WYOMING**

Senator THOMAS. Thank you. I'll be very brief, you've covered it very well.

First of all, let me thank you for holding this hearing. I think it's extremely important and important that we get out to the country to talk about these kinds of issues so that everyone knows about it.

I'm from Wyoming so we have a little advantage of being west of you, Governor, and the wind sort of comes your way so that's always helpful.

We—I guess the main thing that I've discovered over these two hearings is the uncertainty. Everyone whose come, all the scientists, all the people who really study it are very uncertain, so I think that's what we deal with.

Then it's been caught up in this emotional thing. Of course, when you talk about health and children and all those things you try to balance that out with the cost, that becomes very difficult. Carol Browner, of course, has done that specifically and intentionally and so it makes it very tough.

We ought to understand, of course, as you have, Jim, that everybody is concerned about health. What we need to do is find the best way to balance the health and what we do in order to make a living.

So, I'm delighted to be here today. I think we do need to give some great thought to this so that we can preserve our jobs, we can preserve our economy and at the same time do the best we can on health and I think we can do the two things together. I'll submit my statements in the record.

Senator INHOFE. Very good. Next we hear from Senator Jim Hutchinson, who is actually from Fayetteville, AR, so they have a lot of the same problems we have along our adjoining border.

**OPENING STATEMENT OF HON. TIM HUTCHINSON,
U.S. SENATOR FROM THE STATE OF ARKANSAS**

Senator HUTCHINSON. Thank you, Mr. Chairman. I also want to thank you for calling the hearing today. It's good to be in Oklahoma City.

I know Oklahoma City is a city that is familiar with tragedy and disaster. Unfortunately, we had our own tragedy in Arkansas over the weekend with 24 fatalities and 14 tornadoes and 9 different counties that have now been declared a disaster area.

Governor Huckabee, I know, would have liked to have been here today. He is with James Lee Witt with FEMA in Arkansas today and so my heart goes out to all those. We visited a lot of them in the hospital yesterday.

But the President may be flying to Arkansas tomorrow so I felt it was important to be here. I think the importance of this subject was that it was important to continue to come here and to hear testimony today.

I thank you for calling the hearing on the very important subject of these proposed EPA's clean air standards and giving us an opportunity to hear most directly from those who are going to be responsible for implementing the standards, the States and the local governments.

I think also, Mr. Chairman, it's a highly symbolic, important symbolic gesture to have this hearing in the heart of America.

Sometimes Washington forgets that any law, any regulation, any proposal that's implemented has far-reaching effects that cannot be measured from a hearing room on Capitol Hill. While it was important for us to have the hearings in Washington, this is even more important, I think, to be here in Oklahoma City.

For the last month we've had two hearings, which have helped me to understand, if nothing else, how complex these standards are.

The first hearing we heard from leading scientists on the issue, in my opinion, learned exactly how little evidence there is to justify setting such stringent standards.

One thing there was agreement on and that was that more time is needed. In fact, I think most of the scientists that we heard testify said that 5 years was really needed whether they favored implementing the more stringent standards now or waiting; they agreed that more scientific study was needed, more monitoring, more data accumulation, both ozone and particulates. The EPA has chosen the radical and severe recommendations of the scientists.

The scientists, experts in their field, presented contradictory testimony and could only agree on one thing, that they strongly disagreed with each other.

So while some of the scientists felt strongly that the proposal was warranted just as many thought the proposals were not warranted at all.

So, I think, as we listen to the testimony today I will be very interested in hearing how this is going to impact our local governments, our State governments and this mandate that's imposed how it's going to impact business and industry, how it's going to impact the opportunity for economic development in our States. We're all most of all concerned about health and safety.

But when you have limited dollars, both public and private, we have to make some decisions and whether or not the proposed standards are the best way to ensure the health and safety of the American people I think is very, very much in question.

So, I look forward to the testimony today and, Mr. Chairman, I thank you for calling the hearing. I would ask that my entire statement be included in the record.

Senator INHOFE. It will be included in the record and I appreciate you coming very much.

Incidentally, I believe this is the largest number of U.S. Senators we ever had in a field hearing in Oklahoma so I do appreciate all of you coming.

Senator Jeff Sessions, a new member of the U.S. Senate from the State of Alabama.

**OPENING STATEMENT OF HON. JEFF SESSIONS, U.S. SENATOR
FROM THE STATE OF ALABAMA**

Senator SESSIONS. Thank you, Jim, I appreciate being with you and being able to share in this hearing.

I think the single most productive hearing that I've been in in my short tenure in Washington was your first hearing that you called that deals specifically with the science of our clean air.

You were correct in that and we didn't talk about emotional issues. We dealt with would these new standards really help people's health. We found that there was serious disagreement about that among the experts and I congratulate you for going right to the heart of that matter and I also congratulate you for bringing us to the heart of America to meet with the people who will have to implement the regulations that will be agreed upon and passed by Washington.

It is not the Washington crowd that will have to live with it, it's the people in the cities and towns and counties throughout America.

They made a lot of progress. Ozone levels are falling in America and the air is getting cleaner. We are making progress.

I've talked to several people this morning involved in the efforts by whole teams of people to identify in their communities ways to get their communities into attainment of standards and they worked hard at it and it's really depressing to them now to have new standards to be dumped on them and some of them feel like they may not ever be able to meet and question whether or not they can be met.

So, we need to deal with this question. We need to have the cleanest air. We need to have the most care we possibly can for our citizens. We need to make sure that our health is not being damaged by the air that we breathe but we need to do it in a sound and efficient way identifying the best and healthiest way to do that.

We'll be hearing from Governors who—and county commissioners and State people who will be dealing with honest questions about are they going to have to mandate expensive vehicle inspections. Are they going to have to mandate car pooling. What will they do? That's one of the things I want to ask, what can you do to even make modest reductions in ozone standards.

I won't say anymore. I'll submit my remarks for the record.
[The prepared statement of Senator Sessions follows:]

PREPARED STATEMENT OF HON. JEFF B. SESSIONS, U.S. SENATOR FROM THE
STATE OF ALABAMA

I would like to thank Senator Inhofe for holding this hearing today to discuss the proposed changes to the National Ambient Air Quality Standards for ozone and particulate matter. Holding this hearing in Oklahoma City with a panel of witnesses from State and local governments gets to the heart of the problem with implementing the EPA's new standards—it is not the Washington bureaucrats who would bear the expense of trying to comply with new standards:

- it is the Governor who must restrict the building of new highways
- it is the Mayor who will have to force the citizens of his city to car pool
- it is the State Environmental Director who will have to recommend policies to deter economic development
- and most importantly, it is the people, like the family in Alabama who may be pushed into poverty because jobs have been lost or because of the high cost of compliance in the soon to be named "non-attainment" areas.

Under Senator Inhofe's leadership, we held two hearings in Washington on the issue of the EPA's proposed standards. During the first of those hearings we heard from members of the EPA's own Clean Air Scientific Advisory Board, which is a panel of scientists who advise the EPA in proposing standards for air quality. The testimony from those scientists proved that they could agree on only one issue—that the scientific basis for implementing new standards for ozone and particulate matter was incomplete. During the second hearing we heard from the Administrator of the EPA who provided Members of this committee a "sales pitch" for much tougher standards. I have to say that I was disappointed that we did not use that time to wrestle with the complex issues we are facing.

The testimony from the EPA scientists showed that high concentrations of ozone can have an effect, although a temporary one, on the lung function of healthy individuals and can aggravate the lungs of those with existing respiratory ailments. The good news is that ozone levels have been falling for years. Still many States are still struggling to bring their areas into compliance with the existing standards, and I commend the tremendous progress they have made.

What we must determine is whether the EPA's proposed standard for ozone goes too far, too fast as Chairman Chafee fears, requiring a level close to that which occurs naturally while failing to achieve real health benefits for the people who must bear the burden of compliance. During the hearing we heard testimony from Dr. Roger McClellan, former chairman of the EPA's Scientific Advisory Committee. We learned that if New York city was to attain the current standards, there would still be some 28,295 people admitted to the hospital each year for asthma. If the new standards were imposed, that number would drop by 120 individuals or three tenths of 1 percent. I am not suggesting that we ignore the suffering of those 120 people

who might be protected, but I do question whether imposing stricter standards for the entire Nation is the most cost-effective way to solve the asthma problem.

The scientific basis for imposing the tighter standards for particulate matter was also discussed during the first Clean Air Committee hearing. During that hearing, Dr. Joel Schwartz, a member of the EPA's Scientific Advisory Board, testified that he had found a "causal relationship" between the level of particulate matter in the air and premature deaths and hospitalization. He had conducted a study in Birmingham, AL, in 1993 using data collected between August 1985 and December 1988 to support his claim. A study conducted by the National Institute of Statistical Sciences, a group who actually receives funding from the EPA and the National Science Foundation, used the exact same data Dr. Schwartz used for his study with one additional variable—humidity. The National Institute of Statistical Sciences study concluded that, and I am quoting now, "when humidity is included among meteorological variables, we find that the particulate effect is not statistically significant." Is this the type of science the EPA is relying on to justify a tightening of the clean air standards? Testimony this committee has heard certainly suggests it is.

When I asked Dr. Schwartz about this published re-evaluation of his study, he was aware of it. He admitted to me that he couldn't be sure if humidity did or did not have an effect his conclusions.

As a father of three, I know and care deeply about children—I will not support any policy which will put mine or any other child in harm's way. What we must determine is whether there is compelling evidence to suggest a tightening of the standards would have significant health benefit for children or anyone else. I must say that I thought the EPA Administrator's testimony at the Clean Air Committee's second hearing was not about the scientific findings her Agency is charged with gathering, but an emotional appeal to support a policy decision to propose tighter standards.

For example, one chart the EPA Administrator presented to the committee regarding the proposed changes to ozone standards showed that 74 million Americans are protected by the current standards for ozone. Under the new standards, she claimed an additional 33 million children would be protected, an additional 7 million asthmatics would be protected, and an additional 8 million people suffering from respiratory diseases would be protected for a total of 48 million more Americans "protected" by the new standards or a grand total of 122 million for both the current and proposed standards. Apparently, the EPA Administrator believes the population of this country is comprised only of children, asthmatics, and people suffering from respiratory diseases because the number she uses just happens to correspond exactly with the 1990 census data regarding the TOTAL population of areas currently in non-attainment plus the 48 million additional people who live the areas which would fall into non-attainment under the proposed standards (I would like to submit the EPA chart and 1990 census data for the record). Any person testifying before Congress, but especially a Cabinet level official, should come prepared to discuss seriously these important issues. A promotional effort is not what I am looking for. I want to be sure we are doing the right thing before asking the American economy and American people to absorb the huge costs these new standards would bring. The plain fact is that these regulations could cost jobs and make us less competitive in the world.

I am in support of reasonable policies, based on sound science which will protect public health. The testimony which has been provided before this committee so far makes me afraid that the proposed standards put forth by the EPA do not represent a reasonable policy decision, are based on inconclusive science, and cannot be shown to have any real health benefits for our citizens. Implementation of these new standards will definitely have an impact on the people of this Nation, however, it will lead to lost jobs, lost competitiveness in a world market and additional health problems for those children and families who are pushed into poverty.

Thank you. I look forward to hearing the testimony of our witnesses today who will be on the "front line" of trying to comply with the proposed standards if they are implemented.

Senator SESSIONS. Again, I want to say how much I appreciate your leadership and the leadership Oklahoma has provided to the U.S. Senate. You have clearly two of the finest Senators Washington has. It's been a delight to get to know them and my respect for them is unbounded.

I also am delighted to see that your Governor, Frank Keating, and I were U.S. attorneys together in the early 1980's, I've known

him throughout the years and our last opportunity to get together was in my hometown of Mobile less than a year ago when he and Kathy were there to speak to the Salvation Army, that was a wonderful thing for you to do and I enjoyed the breakfast together. Frank, it's good to see you again.

Senator INHOFE. Thank you very much, Senator Sessions.
Governor Keating.

**STATEMENT OF HON. FRANK KEATING, GOVERNOR,
STATE OF OKLAHOMA**

Governor KEATING. Mr. Chairman, Senator Inhofe and members of the subcommittee, it is an honor for me to represent my fellow Oklahomans in this hearing because it is important that our elected officials and appointed officials, our citizens, have the opportunity to review their concerns and their hopes with members of this subcommittee.

I'm especially pleased to see Senator Inhofe is the subcommittee chairman. Senator Inhofe, as the mayor of Tulsa, was very sensitive to the issues of clean air. As mayor I know he told us to turn off our two-cycle mowers and take the bus when I was the vice chairman of the transit authority some years ago there and we as a community and we as a State have been very sensitive to clean air issues.

I believe Senator Sessions, as a former U.S. attorney, has been promoted to glory and I know, Senator Tim Hutchinson, your brother Asa who was U.S. attorney with me as well, also now is a distinguished member of the Congress and a great compliment to both States and obviously to both families.

Mr. Chairman, I want to apologize, after I complete my informal remarks and present to you a formal statement, which I hope would be made a part of the record, I have to go to honor a friend of yours, Jim Pilsticker, who is the head of Arrow Trucking in Tulsa for his role through the Fish and Wildlife Service of creating natural habitat in Oklahoma for migratory waterfowl and migratory song birds and eagles, this is a statement of how sensitive we are to our habitat, how very proud we are of the fact that we have tremendous recreational opportunities in Oklahoma. We do not have any desire as to soil our nest. We want our State to be as pristine as it can be but also as prosperous as it can be.

And for me to join Mr. Pilsticker to be honored in this section of the country as the person who has done most to encourage the development of waterfowl habitat is a statement of our interest in the environment as a State and certainly as a leadership community.

The issue, Mr. Chairman, obviously before us is are the proposed increased standards on ozone and fine particles suggested by the Environmental Protection Agency necessary.

My testimony today, as I've indicated, is formally presented that I would ask to be made a part of the committee record, but informally and formally I'm here as Governor of the State of Oklahoma as well as chairman of Interstate Oil and Gas Compact Commission representing some 26 States, and also as a representative of the National Governors Association representing our 50 State Governors.

In each capacity I have a strong and a lifetime commitment to clean air standards that protect the public health.

However, I think all of us ask the question, and must ask the question, are these standards, these rigid standards issued without full regard for the totality of scientific evidence.

The results of these standards in Oklahoma will be—are very clear and I think will be very damaging. Oklahoma City, Tulsa, and Lawton and some other areas, all of which we are growing, as a developing State we're very interested in bringing new jobs and new industry to Oklahoma but these three cities, with tremendous difficulty, have become containment—or attainment cities, would fall out of attainment with the Federal Clean Air Act.

Existing implementation plans would have to be revised, in our judgment at great cost, and they would have a negative effect on economic growth, something that is very important to us, a State that needs to keep its per capita personal income and encourage high value, high wage jobs, not only to maintain their presence here but to expand and to locate here.

Oklahoma is proud of its progress to date in assuring clean air and the health protection of our citizens.

However, these proposed new standards are the toughest in history, as the members of this subcommittee know. They will have enormous impact on the economy and our ability in Oklahoma to create jobs.

Communities forced into non-attainment would be at a huge disadvantage in competing for new business in industry and jobs. This is especially true, as I know Senator Thomas humorously noted, we're a State that there is not a lot in some sections of our State to separate us from a lot of other States. We have a large agricultural population.

In this section of the State and West have a wind that blows from other places and we're very concerned about the impact that these standards would have on our agricultural economy, our ability to grow the foodstuffs that provide to the tables and for the tables of the rest of America.

Also our ability, in Tulsa particularly, to expand and to provide the income level for the State to provide the education level that our people so desperately need.

An example, of course, is here, Oklahoma City Community College cannot be unless we have the jobs and the taxpayers to make it be and we cannot expect to have the jobs and the taxpayers if we have an arbitrary set of standards that shuts down, and I want to emphasize that, Mr. Chairman, literally shuts down our ability to expand businesses and to attract new business to our State.

We also believe that this will have a profound negative impact on the oil and gas industry, which is the second largest employer in the State of Oklahoma, one that has provided us a tremendous depth to our economy and prosperity.

The non-attaining communities would also face increased regulation and the possible withholding of Federal highway funds.

We are in the legislature, as I speak, and there are members of the legislature present, in the process of trying to dramatically expand our State's transportation infrastructure. We expect to spend a great deal of money this year in doing that. These kinds of things

are very worrisome to us because, obviously, if we can't do this we shortchange our prospects for our young people and we drive them out of the State.

Also, if we can't do this we shortchange the ability of our cities to expand and to grow and to create the tax revenue to payoff the bonds necessary to build highways.

The National Governors Association and the Interstate Oil and Gas Compact Commission have asked for extended hearings. The EPA, Environmental Protection Agency, has complied and we're grateful for that, but they should have taken these objections even more seriously and gone back to square one to re-examine the standards.

The scientific credibility gap, Mr. Chairman, that you noticed, I think is true. The EPA's own clear air scientific advisory committee has failed to agree on the impact, if any, fine particulate matter has on respiratory health.

The current ground level ozone levels before the new standards are very close to natural levels. Is the EPA seeking to go nature one better?

The scientific advisory committee took no stand on the proposed new ozone levels and the raw data has not been made public.

How can we be asked to make a decision that would cost so much when the scientific evidence for that decision is shaky at best or uncertain at best and locked in some ones else's files.

The Competitive Enterprise Institute shows that 72 percent think that State and local government should set pollution levels and criteria and 65 percent of our public think that State and local governments do a better job of protecting the environment than the Federal Government.

As I've noted, Mr. Chairman, and members of the subcommittee, we have no desire to soil our nest. We want a viable prosperous successful but clean and environmental friendly State and we think we can do that, thank you, with very definite and close attention to the science and to the needs of our public, the health needs of our public.

What we need, Mr. Chairman, is a true partnership among Federal, State, and local and industrial concerns to assure a safe and clean environment with due regard for the needs of the economy. Instead, we propose to be receiving mandates based upon questionable science and driven by unelected officials in Washington.

The IOGCC position is that the new standards would have a serious and negative impact on the industries ability to meet our petroleum requirements.

Congress should recall that most oil and gas producers are small businesses, hence the standards must be reviewed, in our view, under the provisions of the Small Business Regulatory Enforcement and Fairness Act as the chairman noted.

The National Governors Association's position is that a cost-benefit analysis must be applied to any new regulation. The EPA should be required to certify that all new regulations will produce benefits that justify their costs and that the EPA and Congress should consider all possible alternatives with an emphasis on non-regulatory and innovative approaches.

In summary, Mr. Chairman, first the proposed new clean air standards would have a very debilitating effect on State and local governments, on communities and our efforts in Oklahoma to encourage economic growth and new jobs.

Second, the scientific evidence supporting the standards is shaky at best and remains a matter of debate among scientists and I cannot imagine us applying onerous standards, expensive standards if we don't have some kind of common denominator with respect to scientific evidence.

And, third, there is no evidence that the standards would significantly benefit the public health.

On those grounds I oppose the proposed standards, urge their rejection and appreciate your being here to listen to the concerns of my fellow citizens.

Senator INHOFE. Thank you, Governor Keating.

Let me ask you a question. You have to go to this other event, normally we'd hear from both of the witnesses then ask questions. Do you have time to do that or should we start with you?

Governor KEATING. I'm happy to hear my friend from Ohio.

Governor Voinovich I know is speaking with—through Governor Hollister here and it's always an honor to have people from Ohio, we need their sales tax revenue, but I'm happy to listen to Governor Hollister's testimony.

Senator INHOFE. Well, Governor Hollister, we appreciate very much your coming. I think I mentioned to you that I was on a radio talk show this morning in Ohio and they all love you dearly there.

They also mentioned that Governor Voinovich has led the way in this subject area and so he regretted he couldn't be here but we're most appreciative that you are here with us today and we're anxious to hear your testimony.

STATEMENT OF HON. NANCY HOLLISTER, LIEUTENANT GOVERNOR, STATE OF OHIO; ACCOMPANIED BY BOB HOSENBURGIE, CLEAN AIR DIVISION, OHIO EPA

Lieutenant Governor HOLLISTER. Yes, Senator Inhofe.

Mr. Chairman, thank you very much. I appreciate the invitation and I too appreciate all of you as U.S. Senators taking the time to have the field hearing to listen to those of us in the States that have, I think, some very serious stories to tell.

Governor Keating, I'm delighted to be in Oklahoma, and I appreciate your hospitality.

As you all know, I represent the other part of the heart of the Midwest in the United States, the great State of Ohio. I'm delighted to be here today because Ohio has a story to tell.

In listening to your opening statements and Governor Keating's well-put remarks, I would agree with everything that has been said that this issue is not about clean air.

Because for almost the last 30 years every State in this country has made clean air and clean water part of their process, part of the government at every level in the State level as well as the local level and that substantial progress has indeed occurred not only in Ohio but throughout the country in trying to meet attainment standards, in trying to deal with the situations that apply to the environment.

But the issue, as it has been appropriately stated, the issue is proposed changes to the standards by U.S. EPA and that this proposal will, in essence, reduce ozone smog levels by an additional one-third and limit particulate matter for the first time ever.

In short, in my opinion, representing the State of Ohio, the proposed standards are draconian. They are not based on sound science and they will indeed be cost prohibitive for all.

But I'd like to take a moment and look at the State of Ohio and what we have been able to accomplish yet as our environmental concerns have progressed.

That since the passage of the Clean Air Act, Ohio has seen peak ozone levels drop 25 percent overall and in some instances up to 50 percent in some of our major urban areas. Since 1972, Ohio industries and businesses have spent more than \$5 billion on capital costs to control pollutants.

In 1993, all seven major metropolitan areas in the State of Ohio were in some form of noncompliance. Today we have only one metropolitan area that remains in noncompliance and they're within .03 of a point of being in compliance. We have only two counties out of 88 in the State of Ohio that are not in compliance with existing particulate matter and they too are very close to attainment. So, we have worked very hard in Ohio to comply with the standards that have been put in place.

What have we done as a State, and I think that was a very appropriate question, Senator Sessions, that you asked, and that in Ohio we have put E-Check.

Now, let me tell you, if you don't have E-Check in Oklahoma you would find that E-Check is one of the most disastrous words you will ever hear. It has been a major sore point for constituents in the State of Ohio.

E-Check right now, even passing 4 million Ohioians who pay \$19.50 to have their emissions checked on their automobile. If they do not pass this test they cannot get their vehicle registration and would have had any number of problems.

Some of our sister States, in Pennsylvania, is examining their whole E-Check program. The State of Michigan has, in effect, suspended their program because of the problems.

Additionally, in Ohio we have put vapor control systems on gasoline pumps in selected areas throughout the State, again, trying to address this problem.

We have numerous industrial controls and voluntary compliance programs throughout the State of Ohio. In fact, the communities are very great being involved in this. Chambers of Commerce in every urban area put out alerts, are in contact with their business and industry saying, you know, what are your emission levels, make sure you check them, it appears we could be in noncompliance.

So, we have a system in place through local government, local chambers, with State government in Ohio EPA to always look to attaining the standards.

You know, Federal reports have shown that through 1995 Ohio public utilities spent \$3.7 billion on air pollution controls. That is more than the combined expenditures of New York, New Hampshire, New Jersey, Vermont, Massachusetts, Maryland, Maine,

Delaware, Connecticut, and Rhode Island. So we feel that we are truly doing our part.

The impact, if these standards are imposed, what would happen to the State of Ohio is in effect all seven of our major metropolitan areas would fail the new ozone standards. And that 21 counties, more than any other State in this county, would fail the new particulate matter standards. In total, we have 88 counties and by EPA estimates, and I have a map here that shows it very dramatically in the red 52 counties would be non-attainment, noncompliance. In the blue areas that's uncertain. We could be looking at an entire State in non-attainment.

This is not an urban and a rural issue. This is an issue that faces everyone whether you live in a major metropolitan area or a small rural county. I'm from southern Ohio. My county's population is 62,000. They will be non-attainment.

We have small counties like in Noble County with 11,000 population, they will be non-attainment. In addition to the cities of Cleveland and Toledo and Cincinnati and Youngstown and Columbus. So we have a very serious situation and a devastating economic impact facing the State of Ohio.

When I look at the particulate matters standards, $PM_{2.5}$ will become something that we're all very familiar with, that there is no State or national monitoring network in place now. In fact, equipment necessary to do this to the standard that U.S. EPA wants does not exist at this point in time. It's been appropriately pointed out, there is no data available on the health risk.

I would also mention for the record that President Clinton in his budget proposal to Congress has placed \$26 million to study the issue of particulate matter and how it relates to health benefits. That clearly points the facts are not established on health risk and particulate matter.

The consequences to the State of Ohio we will have an expansion of the dreaded E-Check and that we will have the opportunity to put in place mandatory clean fuel, and I say that somewhat facetiously, because it looks as though mandatory clean fuel could cost an additional 10 cents per gallon and that there will be more controls, more restrictions on business and industry.

Additionally, we anticipate that there will have to be a reformulation on consumer products, whether that's how long it takes paint to dry or aerosol containers.

Our Department of Development has identified 17,500 manufacturing facilities in our State that cover over 900,000 jobs. This is 80 percent of our manufacturing work force. It is anticipated that all of these companies would be located in non-attainment areas in the State of Ohio and the cost to try and comply would be prohibitive. And that Ohio EPA estimates that only partial compliance cost would be \$760 million annually, that is outrageous.

From my personal perspective, when I look at this issue on the national level it is also a global issue because what is driving U.S. EPA. What promulgated them to reach the point to put these standards in place that are so prohibitive to States in this country.

From my concern it's something that you need to be very aware of because climate control is a global conversation. We have treaties in place. We have discussions taking place right now in Gene-

va. We have an article called the Berlin mandate, which, quite frankly, puts us in a no win situation because we have representatives of the U.S. Government signing treaties in Europe that binds us to limiting further our emission controls while excluding developing countries and I have a problem with that. This is a discussion that needs to be—have a check and balance with the U.S. Congress.

I would also like to reinforce what Governor Keating has said and what you all have mentioned, that you have a window of opportunity as U.S. Senators to examine this issue because I truly believe that U.S. EPA will proceed, they will put these measures in place and you have a 60 day window of opportunity to rescind these measures, to make a comment. On behalf of the State of Ohio I would urge you to do so. Thank you.

Senator INHOFE. Thank you, Governor Hollister.

Governor Keating, I had an experience the other day when I was doing these 21 meetings around the State, one was in Sand Springs, and one of our valued industries, Sheffield Steel, I know you've visited them many times, was there, they now are operating three shifts a day 7 days a week.

One of the things California experienced is that some of the companies that have been operating at that kind of an accelerated program are cut back, it was mandated they be cut back to—in one case it was 4 days a week one shift a day.

Now, one of the many things that you have done very, very well, and I think you followed the lead of our former beloved Governor and U.S. Senator Dewey Bartlett, is in your industrial recruiting effort where you actually go in to the CEO and sit down and talk about what we have in Oklahoma.

I'd have to ask you if these standards are lowered at the number of counties in Oklahoma that even the EPA agrees would come out of attainment what would you tell those CEOs when you go in to sit down in their offices?

Governor KEATING. Well, and—Senator, that is a challenge because those of us who are Governors who not only visit CEOs of companies within the United States but also companies without the United States want to talk about our productivity levels, our educated work force, the tax structure, the regulatory structure, but if they think that there is something out here, a mist, if you will, that will negatively impact their ability to expand or to locate they will not do it.

I mean money and jobs are very fungible. If they think that as a result of something they can't control and that I can't control that they will be discouraged from being successful in my State they will not come. The reality is a developing State like Oklahoma cannot have that happen.

You know, it's one thing for us to catch up with California or to catch up with Connecticut in terms of income. They have an infrastructure in place we don't have. We have to catch up sensitive to our environment but we have to catch up.

It would be catastrophic for our ability to keep our young people in Oklahoma, to expand our job base, to increase the per capita income of our people if I couldn't answer that question with any kind of sense or fact.

Right now to say that these are issues outside of my control, no matter how hard we work as a State, and we have worked as a State, you know as mayor of Tulsa how hard we worked to make our State pristine, it doesn't matter.

Someone who has never been here will tell us what we can or cannot do. That is, in my judgment, anti-Federal and it certainly is completely contrary to the ability of our—the opportunity for our ability to grow.

Senator INHOFE. Governor Hollister, what would your posture be?

Lieutenant Governor HOLLISTER. I would agree with Governor Keating. And we experience this right now.

When any company is looking at Ohio as a place to locate one of the first questions that's asked is what is your attainment or non-attainment status. And you don't even further the conversation. That's the end of the conversation. You may never even know that they're looking at your State. Or if you have an existing industry that wants to expand their expansion plans are automatically limited by the amount of the emissions they put in the air.

So—and I would agree with his comments that it is a very frustrating situation to have to deal with a set of standards that as a State government or local government you have no say in, that someone else made the decision for you and try to explain that a Federal action leads to State consequences.

Senator INHOFE. I use the Sheffield Steel example, but there are many others around. I use it as an example also because when they showed me how they're operating; they're at three shifts a day and the number of people that they employ in northeastern Oklahoma, they made the statement that if this happens and if they are cut down in terms of the numbers of shifts a day they wouldn't be able to find a place in the United States that they could move to. This would cause them to have to look elsewhere, overseas.

Lieutenant Governor HOLLISTER. Oh, absolutely.

Senator INHOFE. I also want to say that it sounds like I'm being very negative about Carol Browner, she happens to be one of my favorite people. You know, you can—one of the things that you can do in Washington is you can truly like somebody and disagree with them and that's the relationship that we have. She's been in my office many times and we've had many conversations.

But I am very critical of her interpretation of the two laws that I described in my opening remarks, the unfunded mandate law as well as well as the flexibility laws that were passed.

The response that she gave, Governor Keating, that this is not an unfunded mandate to the States, such as the State of Oklahoma, because the States are going to have to make the determination as to what they're going to do to come into compliance if the standards are lowered. That this is—that there is no responsibility under the flexibility law for the Federal Government to explain what's going to happen to “small entities” because the States will be doing that.

What's your interpretation of that response?

Governor KEATING. Well, that's the only response she could give to you. I mean the reality is this is a tremendous potential burden on us. The State will have to pay in lost wages and lost develop-

ment opportunities and, of course, we'll have to pay to comply for those operations that we are involved with, but the private sector, of course, that fuels the engine that keeps us alive will have to pay big time.

I think that any time the Government proposes to do something it makes abundant good sense to say, well, how much is this going to cost, will this really do the things that we propose to do.

As I know all of the membership of this subcommittee said at the outset of your presentations, we want clean air, we want clear water, but, you know, there is a level beyond which an enormous additional investment does not provide and enormous additional benefit and that is the line that needs to be found.

We want appropriate scientific evidence to find that line and all of us as a people will lock arms together to go up to that line. But right now when there is confusion and disagreement within the scientific community and we are asking a developing State like Oklahoma to expend enormous resources to kill our ability to grow and to prosper I think it is simply not in the best interest of the country and certainly not in the best interest of Oklahoma.

Senator INHOFE. Thank you. Governor Hollister, you used a couple of figures, one was that the President has in his budget \$26 million.

Are you aware that last year we had in our budget \$28.8 million for the express purpose of studying this to see what scientific basis there is for making changes and that money wasn't spent for that purpose, instead they come out with these recommendations.

The other thing that I wanted to mention, did I hear you correctly, tell me again about the \$3.5 billion.

Lieutenant Governor HOLLISTER. We have our utilities—our public utilities in the State of Ohio have spent on emission control, pollutant control devices, \$3.5 billion through 1995 and this impacts our coal industry.

We're talking about trying to comply with the standards, we have lost over 12,000 jobs in the State of Ohio in our coal industry as a direct result of the last standards that implemented and we did comply, but the expenditure was \$3.5 billion.

Senator INHOFE. Well, you know, if it was \$3.5 billion would you say that the EPA's estimate as to what this cost would be nationwide, \$6 billion might be a little conservative?

Lieutenant Governor HOLLISTER. We think it's very conservative. Because we estimate partial compliance being at \$670 million.

Senator INHOFE. Thank you. Senator Thomas.

Senator THOMAS. Thank you. Let me pursue just a little bit, as the chairman said, when we ask about the cost EPA says, well, we're not creating the costs it's the States as they put in their State implementation program.

Somebody, I think it was our friend from Missouri, said it was like someone shooting a bear then blaming the bullet.

Do you—will you have flexibility as to the way that you can adhere to these regulations enough to reduce the cost?

She indicated you could do different things in the State to alleviate the cost. How do you react to that?

Governor KEATING. I mean obviously Lt. Governor Hollister will jump in and perhaps have a little finer point, but the reality is we

probably all are going to have to do it in much the same way because all of us are first world economies. All of us have—you know, many of us have coal mining operations. We have agricultural operations. We have industrial operations of various sorts and, of course, we have service industries, but we'll all have to do it in about the same way.

It's just that incremental additional benefit that is enormous cost that we question. As we were all growing up we competed against 49 other States, you know, now we're competing against 49 other States and 140 other countries. This is—we must do this right or don't do it because it is going to be expensive.

If we make sure that the expense is justified, is worthy of our investment, it really will have a profound positive impact on public health, then that's something we can debate but when the scientific community is uncertain, there's some that say it really won't have much impact. To have us have to do it virtually in the same way at an enormous cost and assurance that we will not have the job growth and the income growth we need to provide for our youngsters.

Lieutenant Governor HOLLISTER. I would concur with the Governor. I think that the interesting conversation or the explanation that they just simply propose standards and the responsibility therefore is ours and therefore the responsibility is not at the Federal level it is double speak and, indeed, is it the bullet, the gun or the bear.

But from Ohio's perspective, you know, you've got latitude in any number of standards, as it has been explained to me, that's not the problem. The problem is, the bottom line is you still have to implement them.

In implementing changes or increasing emission controls on any given factory or plant or we're going to move into other dimensions now too it seems, it's going to cost money to do so. And to make that kind of an expenditure, as the Governor pointed out, without sound science makes no sense.

Governor KEATING. Senator, if I may say this, and I apologize, I've got to go, but how do you do this in an agricultural economy consistent with the most modern technology. I mean how do you not turn the earth.

Last year we had a very severe drought. We had to turn the earth. Obviously there are particulates that will go into the air as a result of that. You've got to turn the earth. You can't, you know, not do that. I don't care how modern your technology, you have to plant seeds, you have to harvest corn, you have to harvest wheat, you have to harvest cotton, those products in our State there are only certain ways you can do it.

What it will do, it seems to me, is reduce the amount of harvesting done, reduce the amount of planting done, reduce the amount of expenditure and investment in the agricultural sector, which, of course, will dramatically raise food prices for what purpose, that's what worries us, where is all this leading us.

Lieutenant Governor HOLLISTER. I think the other point, even to comment on what the Governor said, we're looking at major highway construction in Ohio, may have to stop or be carefully monitored.

When you're talking about increasing Oklahoma's infrastructure system you're going to face the same problem that even highway construction will come under some sort of monitoring especially when it comes to particulate matter, very difficult situation.

Senator THOMAS. We had a little trouble with forest fires, they sort of mess up the air around town.

Senator INHOFE. Senator Thomas, if I could interrupt you for just a moment.

Since Governor Keating has to leave there was one question that Senator Sessions had of you before you left and then I'd ask Governor Hollister if you could remain. Thank you.

Senator SESSIONS. Governor Keating, I think one thing that we need to not lose sight of is the fact that the reaction of the Governors as a whole, not just the two of you, but the whole Governors conference is it fair to say is very concerned about these standards and are very troubled that they may hurt the economy of this country?

Governor KEATING. Well, Senator Sessions, that is not a partisan issue. Democrats and Republicans alike, the NGA, as you know, represents both parties as well as the Independent Governor, the Governor King of Maine, and all of us are concerned with the science, with the dynamics, with the results, with the economic costs, with the impact on our States to grow.

Of course, once again, with people that we can't get hold of who will make these decisions, will force us to do things without any responsibility or any response. We find that very troubling.

That is from the National Governors Association, people of both parties, both concerned with where this is leading us.

Senator SESSIONS. And the Unfunded Mandate Act that passed, what, 2 years ago, you felt would give you protection for this very kind of thing; is that correct?

Governor KEATING. Absolutely. I think that it does apply. I don't care how nicely you might want to lawyer this language, the fact is this is something that's going to cost us. The issue, of course is, does it make sense? Is it cost effective? Will it contribute to public health and safety? And if the answer is we don't know then why are we doing it.

Senator SESSIONS. Well, it's easy for somebody to get the credit or to pass a rule to say cleanup the air and walk away and you have to do the job.

Governor KEATING. That's correct.

Senator SESSIONS. That's good—that's the kind of problem I think we're dealing with at the most basic level.

Governor KEATING. Yes, sir.

Senator SESSIONS. Some people, you know, and I don't know all the answers and I'm learning but I can see where the dynamics lie and it's going to—the burden is going to fall on the States and the localities.

Governor KEATING. Right.

Senator INHOFE. Governor Keating, thank you very much. I know you do have to leave and I appreciate your coming by and spending this time with us.

Governor KEATING. Thanks, Mr. Chairman. I told Lt. Governor Hollister, I apologized to her to have to take all these questions but, I'm sorry, I do have to go to this luncheon.

Senator INHOFE. I have a feeling she can handle it.

Governor KEATING. I think she can too.

Senator INHOFE. Thank you, Frank.

Senator Thomas, did you want to say something?

Senator THOMAS. I just have one more. I guess I missed—we hear a lot of discussion from the New England States, you alluded to it in your statement, that they're concerned about the interstate movement of pollution and that they are being affected by the coal fire generation in the midwest. How do you react to that?

Lieutenant Governor HOLLISTER. That is a statement that's been repeated often. In the last several years a group has been put together, in fact it's nationwide—the OTC, the Ozone Transportation Group—to study this issue.

According to initial scientific data, the State of Ohio's airborne pollutants stay within a hundred mile radius. Indeed, airborne particulate matter from Ohio could be drawn in a circle with a hundred mile radius. That area's air is what we would have to concentrate on for environmental control, not the New England States.

So, to learn these facts was very heartening because we toss around words. We talk about, even from the New England States, saying, well, those of you, the old industrial States are polluting us. And how is that? Never has there been sound science to say that's actually happening.

So, the OTC group are the formation of those groups, multiple States have been very, very helpful because we feel very strongly that within a 100 mile radius is where you look for airborne particles, not 500 miles or 800 miles.

Senator INHOFE. Thank you, Senator Thomas. Senator Hutchinson.

Senator HUTCHINSON. Governor Hollister, thank you for your testimony. I notice that what Governor Keating and yourself both focus a great deal upon is the disincentive that would be created for investment for business and industry for the very real competitive disadvantage that many States would be placed at and, of course, I guess Ohio's procedures being more developed than Oklahoma or Arkansas.

This is a huge issue in the State of Arkansas, a State that has for many years not experienced great economic growth. We've not seen per capita income increase like we would like and not seen the jobs created and now that's happening. And to many of us, as we look at economic growth in Arkansas, we see that being jeopardized by these kinds of very onerous and not justifiable standards.

But one other, I think, concern that has not been raised about what might happen is the impact upon ISTEA funds.

I serve—our committee in fact will be reauthorizing the Intermodal Surface Transportation Efficiency Act, the Highway Funding Bill and Highway Policy and one of the conditions, of course, that EPA has the right, if they find a State out of attainment, to withhold those transportation funds from the State and that in Arkansas would also be very devastating, as I'm sure it would impact—

Lieutenant Governor HOLLISTER. It would be in Ohio also, Senator, it would be very detrimental.

Senator HUTCHINSON. One of the—when we had Administrator Browner, one of the areas that I questioned her was regarding the time table for establishing sufficient PM_{2.5} data and comparing that to the timetable that the Clean Air Act would require Governors to act and for them to comply, and she agreed that it would really take about 5 years for the monitoring network and for everything necessary to be in place.

But when you read the Clean Air Act the law requires that a year after a regulation is promulgated Governors must submit a list of non-attainment areas in their State.

I remember Administrator Browner brought this very impressive looking chart that demonstrated the monitors that currently exist to monitor PM_{2.5}. While there are thousands of monitors for PM₁₀ there were a grand total of 51 monitors nationwide for PM_{2.5}.

So to promulgate a standard this year without even having a network in place to monitor that data would seem to be almost impossible, putting the States in almost an impossible situation.

Now, you gave a number of statistics and I'm really curious, the 2 counties out of 88 are out of compliance currently, so you said very well.

Lieutenant Governor HOLLISTER. Yes.

Senator HUTCHINSON. That if these new standards were imposed 21 counties—

Lieutenant Governor HOLLISTER. Twenty-one counties, that would be more than any other State.

Senator INHOFE. Out of 88?

Lieutenant Governor HOLLISTER. Out of 88.

Senator HUTCHINSON. Out of 88. And how \$760 million annual cost, 17,500 businesses and 900,000 jobs would be located in the non-attainment area, is that—

Lieutenant Governor HOLLISTER. That's 80 percent of our manufacturing work force that are located in major urban areas, which would fall into non-attainment.

And what—you start almost splitting hairs because you're talking about particulate matter attainment, you're talking about ozone attainment and we break all of that down in the State of Ohio, but what it comes down to is that 52 counties, and that is a very conservative estimate, would be non-attainment either for ozone and/or particulate.

Senator HUTCHINSON. How, without these monitors, how could you—how did you arrive at—are these just pretty rough estimates or do you feel comfortable, how—

Lieutenant Governor HOLLISTER. These are estimates from U.S. EPA as well as Ohio EPA evaluating their data.

Again, that's part of the frustration. When we're talking, and I showed you the map, these are just preliminary estimates, they're very conservative, and that's sort of a baseline and we anticipated it to be much worse than that but it's a place to start. They're called hardcore guesstimates.

Senator HUTCHINSON. Hardcore guesstimates.

Lieutenant Governor HOLLISTER. That's what we're dealing with.

Senator HUTCHINSON. The requirement is that within a year when the regulation is promulgated the Governors must submit a list of non-attainment areas in their State. Without the 2.5 monitoring network in place would it even be possible for you to provide that information within a year?

Lieutenant Governor HOLLISTER. I think it would be very difficult to do and I think each State has a very active environmental protection agency. And, again, we would be putting forth our best guesstimate.

I have with me Bob Hosenburgie, who is the head of our Clean Air Division for Ohio EPA and he might want to address that specifically if that's permissible, sir.

Senator INHOFE. That would be, yes.

Lieutenant Governor HOLLISTER. Bob.

Mr. HOSENBURGIE. Thank you, Mr. Chairman and members of the committee.

The specific item you hit upon, in Ohio, although we have an extensive monitoring network, we do not operate any monitors for $PM_{2.5}$. Specifically because U.S. EPA has not approved a methodology to do so. We did not want to invest the money in monitors to attempt to measure $PM_{2.5}$ to only later find out that's it's not the approved methodology and that those—that that equipment would not be useful anymore.

So, you are correct in that I do not know how we would present to U.S. EPA information within a year as to what areas would be in attainment or not attainment because in fact the data does not exist.

And to just further explain. The 21 counties are based on U.S. EPA's proposal, the data that they gave out and they also say that it's subject to significant uncertainty.

Senator HUTCHINSON. So, within a year you're not certain that you could with any degree of confidence even come up with a list of non-attainment areas much less a plan as to how to control and mitigate the new standards?

Mr. HOSENBURGIE. Yes, that is correct. And the other thing, just go back to a bit of the history in the development of the PM_{10} standard where we are today, we used to have total suspended particulates and now we are PM_{10} .

We had 2 or 3 years of monitoring PM_{10} before we had to submit those designations to U.S. EPA. We're allowed to do monitoring and had monitoring in place so that when EPA changed from total suspended particulates to PM_{10} we had some data base and something real to submit those and fulfill the requirements in the Act.

Lieutenant Governor HOLLISTER. And we have no data base now.

Mr. HOSENBURGIE. That is correct.

Senator HUTCHINSON. Well, it seems to me what EPA is proposing to do is to propose a new standard, a more stringent standard, that cannot—you cannot physically—you cannot—the States could not possibly comply simply because the monitoring network is not in place and the data is not available. Is that fair?

Lieutenant Governor HOLLISTER. Yes, that's an accurate statement. One other thing, and I don't have the figures in front of me, we have a number of areas in this country that are in noncompliance right now, they are non-attainment, and the U.S. EPA has ad-

mitted that for all practical purposes it's almost impossible for them to reach an attainment status. What are those folks going to do when this type of regulation is put in place let alone those of us who are almost in a 100 percent compliance.

Senator HUTCHINSON. But you have two counties—

Lieutenant Governor HOLLISTER. And now we have two—we are so close with those two. I mean we're working very closely with the communities. Everyone is involved in trying to put it over the top and make sure that we're OK.

Senator HUTCHINSON. Would you agree that it would make a lot more sense, since Administrator Browner acknowledges that it will take 5 years for that monitoring network and for everything to be in place for the States to comply, that to go ahead and to begin to work toward the more stringent monitoring network, accumulate the data, build a scientific case, if such a case can be built for the more rigid standards, before the new regulations are imposed upon—

Lieutenant Governor HOLLISTER. Oh, absolutely. It's called common sense.

Senator INHOFE. Thank you, Senator.

Let's keep in mind, however, when you say common sense, we're dealing with Washington.

Senator SESSIONS.

Senator SESSIONS. Well, I hear how much Oklahoma has done. I know Alabama has worked real hard on this project, what Jim did in Tulsa and how much community involvement you've had in the whole State of Ohio to make these major improvements in your air quality.

Let me ask you, do you think this—having these—now just as you're reaching that goal, to have these huge higher standards in place, empaneled, would that—what kind of impact would it have on the enthusiasm of the people whose been working, and their view—

Lieutenant Governor HOLLISTER. Senator, I invite you at any time or I'll be glad to send you the clips from individuals who are dealing with E-Check right now. They are most unhappy with this. Any number of problems. And trying to put these programs in place to address some of the issues we've been discussing.

I define progress as steps forward and these new standards are not progress. They are steps backward.

I qualify that by saying, again, that there isn't any State that isn't environmentally conscious and they've been putting things in place and working with local government to continue to make a better environment, that just makes good sense for quality of life and for productivity and selling your State. To me these standards are a step backwards.

Ohio is an old industrial State. Seven years ago when you talked about Ohio the word rust belt was attached to the State of Ohio. We have worked so hard, not only to be in compliance with the Clean Air Act, but to improve our industrial commercial base. As Governor Voinovich is fond of saying, the rust is off the belt. For us to go backward is something that we will absolutely fight.

Senator SESSIONS. Well, I just had a conversation recently with a very successful businessman who said when I up the standards,

when I up the bar for my company we have a plan and we know how we're going to get there before we ask our people to do it otherwise it's depressing to everybody when you have a standard and there's no real way to get there.

I do, I know that every year older and less efficient cars are going off the market, which is good, and not being used, but in Alabama we're a poor State. We've got a lot of people that go to work with cars that may not meet those standards and it's going to fall disproportionately on the poor people of America. In Alabama if they've got to have checks and spend \$200 and \$300 on a car that may not be worth \$300 to get it up and that does worry me some.

Let me ask you this. I was thinking about these numbers, you mentioned \$5 billion had already been spent in Ohio?

Lieutenant Governor HOLLISTER. Yes.

Senator SESSIONS. That—in those kind of figures, Jim, I think it's rather odd that EPA has spent—hasn't spent the \$26 million that it would take to tell what these things may play on to be.

I had the opportunity on an airplane a few weeks ago to sit right next to the air quality scientist for the Tennessee Valley Authority. I asked him what would it do to them and he told me that it would cost \$1 billion for TVA to meet these new standards, and Craven Crowell, the Administrator of TVA told me the same thing. So, the figures of \$6 to \$8 billion used by TVA that it would cost to get in compliance nationally appear to be really far below reality.

I will not pursue the matter anymore other than to ask you one more thing. If an area is not in compliance and a new business wants to build there, or an old business wants to expand and it has only modest but some modest increase in particulate or ozone emissions, do you know exactly what would have to be done before they could build?

Lieutenant Governor HOLLISTER. I know that would certainly be a point of discussion and I would ask Mr. Hosenburgie to address the particulars.

Mr. HOSENBURGIE. Mr. Chairman, Senator Sessions, the—there are something that is both in the Clean Air Act and U.S. EPA regulation, it's called the Emission Offset Policy.

What it requires is that if it's something called either a major new source going in or a major modification, what has to happen is that company has to find emission reductions equivalent to or a little greater than what it projects it will put out after it expands.

So, it has to go around shopping for emission reductions from other companies and obtain those before it can build. That is always a significant hurdle.

Going back to some of the previous questions. Many times in dealing with new companies having to come in the first thing they ask for when they come in to meet with our agency where are the non-attainment areas. They just frankly say we won't go there. And we'll say, well, maybe we'll help you look for the offsets. And they say, no, don't bother, we just do not want to build in a non-attainment area.

Senator SESSIONS. This puts a major detriment on the entire non-attainment area for economic growth, I don't think there's any doubt about that.

Lieutenant Governor HOLLISTER. Oh, absolutely.

Senator SESSIONS. Thank you, Mr. Chairman.

Senator INHOFE. Thank you. Let me just add one comment. I think it was Senator Hutchinson who brought up this whole idea of ISTEPA and its effect. We happened to have Rodney Slater, the newly appointed Secretary of Transportation in before our committee just this last week and we asked him the same question.

I think as to what kind of costs would be involved in terms of non-attainment States, and obviously—it became obvious to us that the amount of money that is being appropriated wouldn't come close to meeting those costs.

Any other questions for Senator Hollister?

Well, thank you very much Senator Hollister—I'm sorry, Governor Hollister, I appreciate very much your coming. I do know that your Governor is the, I think, the chairman of the—

Lieutenant Governor HOLLISTER. He's the incoming chairman of the National Governors Association and feels very strongly about this issue.

Senator INHOFE. I know he does, I had occasion to be with him on such a panel in Washington and I think everything that you have said he would agree with.

Lieutenant Governor HOLLISTER. Thank you.

Senator INHOFE. Thank you very much.

We're going to have seventh-inning stretches between the panels so if anyone wants to stand up we'll take about a 3 or 4 minute recess while I introduce the next panel.

I'd like to make a comment, however, that we have three Governors who said that they want to submit their testimony, and they are Governor Nelson of Nebraska, Governor Schafer of North Dakota and Governor Huckabee from Arkansas.

I would also suggest for the witnesses who just testified and those who will be testifying in a few minutes, that we may have questions that we will submit and request that you answer those questions in writing.

We'd now ask that our next panel come forward. Our second panel is the Oklahoma State Senator Paul Muegge on behalf of the National Conference of State Legislatures. I'll let Senator Muegge explain what he does with that Conference of State Legislatures.

Mayor Susan Savage, my mayor of my city, Tulsa, OK. She'll be speaking on behalf of the U.S. Conference of Mayors. I believe that Mayor Savage is the chairman of the Energy and Environment Committee for the U.S. Conference of Mayors. We appreciate very much your speaking in their behalf.

We'll ask you when you're responding to questions whether you're speaking for yourself or for the association.

We have Mark Schwartz of Oklahoma City and he'll be speaking on behalf of the League of Cities. I believe, Mark, you are the chairman of a comparable committee with the League of Cities, we'll let you identify that committee, if you would.

Mayor Patrick Henry Hays of North Little Rock, AR. I was riding in from the airport with Mayor Hays and I commented that I tell my friends in the U.S. Senate quite frequently, if you really want to know what a hard job is you become mayor of a city, that's a hard job.

Senator THOMAS. Mr. Chairman, you've got a lot of faith in this seventh inning stretch, so many escape when——

Senator INHOFE. Well, they did, didn't they. They wouldn't do that in Wyoming, would they?

Senator THOMAS. Of course not.

Senator INHOFE. The last time I was in Wyoming at one of these hearings I found that their attention span up there was a little shorter even than ours.

[Recess.]

Senator INHOFE. Since our last two panels have four witnesses each we're going to ask that we try to follow some type of a time element here, let's say 6 minutes for each opening statement and maybe 5 minutes for each round of questioning and see how the time goes. Don't feel badly if you have to go a little bit over.

However, your entire statement will be submitted for the record.

**STATEMENT OF HON. M. SUSAN SAVAGE, MAYOR OF TULSA,
OK, FOR THE U.S. CONFERENCE ON MAYORS**

Ms. SAVAGE. Senator, I know we've not officially reconvened here but on behalf of your city of Tulsa I want to present to you a centennial pin as Tulsa is celebrating its 100th anniversary this year because we don't want you to forget Tulsa.

Senator INHOFE. We won't. Thank you very much.

A lot of people get a little confused about that, Susan, because they say, wait a minute, how can you have your centennial when Oklahoma didn't become a State until 1907. We had to explain to them when I was mayor of Tulsa.

Ms. SAVAGE. You have to explain this. But Tulsa was progressive even then.

Senator INHOFE. It was progressive even then and you might——

Ms. SAVAGE. It just took the rest of the State a while to catch up.

Senator INHOFE. Do you want to share with them what Tulsa means and——

Senator HUTCHINSON. Was it at that time, Senator, mayor of the Nation of Tulsa perhaps.

Ms. SAVAGE. It was Tulsie Town, which was settled by the—Tulsa was settled by the Creek Nation, Muskogee Creek Nation in the 1800's actually about 50 years before we were incorporated as a municipality.

As the Senator knows, the actual incorporation occurred in Muskogee, OK, which was at that time Indian Territory in 1898. We cannot find Tulsa's actual original articles of incorporation.

We are told that—we thought they were in Muskogee, then we thought perhaps they were in Oklahoma City and we thought—were told they might be in Fort Worth or in Dallas. We've since been told that perhaps they burned but I've had a couple of people I know from Muskogee say, don't worry, if you need some new ones we can get you some that represent any age possible.

So, there's a lot of folk lore but we're having a wonderful year of celebration which brings together our Creek heritage as well as the very diverse nations in Tulsa.

Senator INHOFE. Well, then why don't we say that Mayor Savage and myself as a former mayor of Tulsa, invite everyone to come and celebrate our centennial with us in Tulsa.

Ms. SAVAGE. Thank you.

Senator INHOFE. We're very pleased to have this. Mayor Savage, I think your dual role here in energy and environment for the U.S. Conference of Mayors is significant. I know you've attended panels throughout the country and we appreciate your making your time available for us today.

Ms. SAVAGE. Appreciate the invitation. Thank you.

Are you ready for me to start?

Senator INHOFE. Yes, ma'am.

Ms. SAVAGE. One of the things I've found in this job I suddenly have to wear glasses to read so let me don these and begin.

I'm very, very pleased on behalf of the Conference of Mayors as well as the city of Tulsa, and I will try my best, Senator, to keep in mind that I am here on behalf of the Conference of Mayors to address this Senate subcommittee and wish to welcome those of you to this wonderful State.

There is a tremendous amount of documentation. I just learned, Senator, from your aide, Mr. Edwards, that our documentation did arrive. There was some question but it has arrived for everyone to receive.

The primary responsibility of any mayor is to protect the public health and safety of the citizens in our community.

While air quality is most certainly an important public health issue the proposed new air quality standards encompass far more than just a debate about the levels of ozone and particulate matter that we will determine to be acceptable in our air. The outcome of this discussion will speak volumes about the livability of our cities well into the future.

Clean air is a laudable, responsible goal. Governments, industry, and citizens have an obligation to ensure that the air we breathe is clean and safe across this country.

Yet, the discussion of the proposed new air quality standards is being held in isolation from the discussion of any implementation plans for the new standard raising many questions for the leaders of our cities. Will communities be held to a more severe standard for pollution which originates in and is transported from other areas.

Will communities be held responsible for the hydrocarbon emissions of those automobiles driving into or through an urban area on a daily or just a periodic basis? How can communities mitigate the effects of unfavorable weather patterns which contribute to the ozone levels due to high temperatures or a lack of wind?

In fact, in Tulsa where the air quality has continued to improve we often say that Tulsa doesn't have an ozone problem. We have a weather problem on some days.

The discussion of the proposed new air quality standards is being held without consideration of the many significant and substantial policy decisions this committee in fact will face this year in its deliberations on the reauthorization of ISTEA, brownfields, Superfund, the future of Congestion Mitigation Air Quality funds and other significant environmental policy issues which dramati-

cally impact the livability of our cities and for which well coordinated policy goals need to be articulated and pursued.

Talk to any mayor of any size city and what you hear is the same, years of federally imposed mandates to meet uniformly applied environmental standards have contributed to urban sprawl, creating a greater reliance upon the automobile, while at the same time reductions in public transit operating dollars and the proposed elimination of the Congestion Mitigation Air Quality funds remove a central tool for our communities who work to improve air quality.

In fact, cities like Tulsa, which has made enormous strides toward cleaner air and remained in compliance with air quality standards since 1990, are penalized by receiving fewer CMAQ dollars than other cities which have not taken such pro-active positions, measures or who went into attainment after 1990.

Let me give you one quick example. Victor Ash, who is the mayor of Knoxville, TN, former Conference president, has been working with me very closely on behalf of the Conference on this issue.

Knoxville recently reached attainment, is now in a maintenance position, they received \$1.2 million in CMAQ, Tulsa just received \$400,000. We're not in maintenance we're just in attainment.

Mayors across the country whose cities are currently in attainment and who have worked to maintain that status, need to understand the purpose and the value of being redesignated into non-attainment, which would be the effect if the standard as proposed is promulgated. It is unclear how this causes an improvement in air quality.

There are currently more than 500 counties nationwide with monitoring stations, 11 percent are now in non-attainment. With this new proposed standard 70 percent would immediately go into non-attainment, which includes Tulsa and Oklahoma County.

A health benefit analysis is the basis for the recommendation to change the standard, yet the lack of inclusion of an implementation strategy, no commitment to adequate funding for impacted communities, and no definitive knowledge about the precursors of ozone impede progress toward the creation of effective local responses and supportable community consensus which blames the goal of clean air with responsible business growth.

Other pressing matters need to be addressed as part of this discussion, even if the rules for implementation evolve subsequent to the promulgation of the standard. As a group of diverse communities, cities question the wisdom of putting the two standards, ozone and particulate matter, in the same category. While their effects may be similar in the health based data, the available technology to monitor the two pollutants vastly different.

The country is ill-prepared to monitor for 2.50 particulate matters since few monitors exist. Additionally, there are no guidelines for their placement and evaluation, leaving community leaders unable to construct a workable strategy.

In the materials released from the Environmental Protection Agency there has been mention of development and implementation of innovative technologies.

Cities are interested in being part of any initiative which involves new technology. At the same time we would like to see the agency acknowledge and credit some of the effective pollution re-

duction methods which use little or no technology but are based on public awareness and leadership commitment.

For example, Tulsa's nationally recognized ozone alert program or voluntary alternatives to commute program and voluntary lowering of the re-vapor pressure, which our industry has undertaken.

Cities has more questions than answers about the proposed new standard at this point. Have other measures to improve our air quality been examined as we as a nation strive to improve air quality? Does the focus on a more stringent standard provide the impetus necessary to generate the public and private support to provide a desirable air quality? We encourage further research to explain the origins of precursors for ozone.

I see I'm running a little bit short on time so let me skip to one additional point and then we can, perhaps, cover more in the question period.

In Tulsa we created the first—the Nation's first Flexible Attainment Region, or FAR agreement, in partnership with the EPA, which is the model being used by other communities for environmental regulation.

The FAR allows an area to custom design programs to improve air quality when there is a violation of the standard and to add more measures as they are necessary, without redesignation to non-attainment. These partnerships should be encouraged to local—to ensure local responses to air quality concerns. They make sense, provide flexibility and enable us to move from the cookie cutter approach to environmental regulation and to work with our State governments and our local leaders to make the decisions about what works in our own communities.

Mayors care deeply about the health and safety of their citizens. We are prepared to be part of a process which results in progressive, sensible environmental policy which can be achieved. In a well coordinated effort we want to construct an air quality solution we can defend to our citizens. There remains much work to be done on this.

Thank you very much.

Senator INHOFE. Thank you, Mayor Savage. You are to be commended on the FAR program. I think that was an effort where a lot of levels of Government worked together and it makes sense.

Ms. SAVAGE. Thank you.

Senator INHOFE. Senator Muegge, would you identify the—there is a group that you're working in within the, I believe, the Council of State Legislators.

STATEMENT OF HON. PAUL MUEGGE, OKLAHOMA STATE SENATE, FOR THE NATIONAL CONFERENCE OF STATE LEGISLATURES

Mr. MUEGGE. Yes, I will address that in my remarks.

Chairman Inhofe, we appreciate you bringing this committee to Oklahoma and welcome the other members of the committee to the State of Oklahoma to listen to our concerns about this issue.

I will be testifying on behalf of the National Conference of State Legislatures. I serve presently on the Agriculture and International Development Committee of the National Conference of State Legislatures. I am chairman of the Senate Agriculture Committee here

in the State of Oklahoma and also serve as vice chair of the Energy Environmental Resources and Regulatory Affairs Committee here in the State Senate.

I appreciate the opportunity to join you today to discuss the proposed changes to the National Ambient Air Quality Standards for particulate matter and ozones.

The National Conference of State Legislatures, NCSL, is the bipartisan organization that represents the Nation's 7,541 State Legislators. We assess Federal legislation and regulation to ensure that State and Federal responsibilities are appropriately sorted out. We further work to remove impediments to successful implementation of Federal law and regulations. Also, NCSL serves as the key resource for State lawmakers for information and analysis of Federal legislative and regulatory action on environmental and other issues.

NCSL is a strong supporter of the principles underlying the Clean Air Act Amendments of 1990. NCSL has repeatedly and forcefully stated its view that the Federal Government should implement and maintain an environmentally sensitive and cost effective clean air policy that establishes minimal national ambient air quality standards in cooperation and consultation with the States and with local governments.

NCSL supports minimum Federal standards for ambient particulate matter and ozone. Protection of human health and the preservation of the environment are a top priority for our States. NCSL urges EPA to proceed diligently with full implementation of the Clean Air Act to achieve healthy air quality for the public and the environment. Specifically, NCSL believes that both stationary and mobile sources must reduce emissions of ozone and particulate matter precursors, nitrogen oxide, and volatile organic compounds.

NCSL does not process scientific or technical expertise required to evaluate and comment on the specific standards set out in the proper rules. NCSL believes it would be imprudent to make educated, but not expert, guesses regarding the support or opposition to the proposed standards.

However, NCSL has serious concerns relating to the process of the promulgation of the proposed rules to the revised standards for ozone and particulate matter. The concerns result largely from the failure of the U.S. Environmental Agency to comply with Federal law and Presidential Executive orders on unfunded mandate relief. The concerns do not focus on the new standards or the underlying science that is the basis for the new standards. NCSL refrains from commenting on the content of the proposed rules of the new particulate standards and revised ozone standards.

My testimony will focus solely on the process by which EPA developed the rules and its failure to comply with provisions of the Unfunded Mandate Reform Act of 1995 and two Presidential Executive orders.

NCSL asserts that in order to adhere to the provisions of the Unfunded Mandates Law and Executive Orders 12866 and 12875, EPA is required to:

No. 1, assess the full cost of State compliance with the revised standards;

No. 2, disclose all Federal resources available to States for compliance activities;

No. 3, identify and assess all alternatives to the proposed revisions and select the least burdensome and most cost effective options; and

No. 4, consult and work closely with the State and local governments during promulgation and implementation of any revised standards.

NCSL also requests that the EPA provide full funding federally and complete guidance for the State implementation.

And also that they publish detailed explanations of the reasons for revising the standards.

NCSL makes these recommendation as an organization with a commitment to the Clean Air Act. NCSL believes the Clean Air Amendments of 1990 address important air quality issues and are essential to protecting public health and environment.

At the same time, in order to meet the goals of the Clean Air Act, Congress and the EPA must fulfill their responsibilities to provide financial and technical assistance to the States. Moreover, EPA has a legal and ethical obligation to meet the requirements of the unfunded mandates and Executive Orders 12866 and 12875.

Thank you.

Senator INHOFE. Thank you, Mr. Muegge.

Mr. Schwartz is one of the individuals who has an abundance of knowledge in this area. He attended a couple of the meetings that we had around the State and I appreciate very much you bringing that expertise to those meetings as well as to this meeting.

**STATEMENT OF HON. MARK SCHWARTZ, OKLAHOMA CITY
COUNCIL, FOR THE LEAGUE OF CITIES**

Mr. SCHWARTZ. Thank you, Mr. Chairman.

Let me, again, welcome you and the other Senators on the behalf of the city of Oklahoma City.

Senator Hutchinson, let me express my condolences for the losses in your State this weekend.

As I told Senator Thomas, I've been to Gillette and it has great air there and I love the State.

I am here, Mr. Chairman, both as council member from Oklahoma City but I am testifying as the president of the National League of Cities on behalf of the 16,000 cities and towns across the Nation that we represent regarding EPA's proposed new standards for ozone and particulate matter. I formally chaired the NLC Energy and Environment Committee a number of years ago.

I would refer you to a copy of the National League of Cities resolution of December 1996, which is attached to my full statement which has been submitted to the committee.

We are an organization that developed policy resolution very quickly after the proposals came out in December during our annual meeting in San Antonio.

I would concur with many of the statements we've heard from Governor Keating and Mayor Savage that as municipal officials that we concur with initiatives to protect health in our cities. We care about the communities and the people who live there. We want to be able to assure our citizens that the air they breathe, the

water they drink and the rivers, lakes and streams in which they play meet the highest and safe as possible health standards in this country that we can provide as local officials.

I can bring little to the debate about smog and soot as a scientist. However, we do have appropriate standing to raise significant concerns about the process by which they were developed and are being proposed as well as the potential for imposing exceedingly costly new Federal mandates on the citizens of this country that may yield few, if any, benefits.

There are a number of areas that I would like to address today, Mr. Chairman. First I think there's an issue of credibility. Many of the State implementation plans developed as a result of the 1990 Clean Air Act Amendments are just now being implemented. NLC played a very big role in the amendments for the 1990 Act.

The plans have not been in effect long enough to determine their impact. The implication, at least for the uninitiated, that what is currently being required is meaningless or futile. If significant additional resources are to be committed to further reductions in pollutants, there must also be adequate assurances that these investments will yield at a minimum appreciable health benefits.

We are also troubled by the absence of adequate and basic information with respect to $PM_{2.5}$. It would seem appropriate to us that before issuing a new set of requirements it might be helpful to know where it is a problem, how extensive is the problem and whether it's the pollutant or is it a subset or constituent of the pollutant that in fact is causing the problem.

In connection with science, it appears clear from the recent reporting and from testimony given at your recent hearing, that there is a significant disagreement with the adequacy of the science on which the proposed standards are based.

We're concerned that we may be moving toward requirements to regulate naturally occurring phenomena, such as windborne sand from beaches and deserts, or pollen from natural vegetation.

It is very incredible and frustrating to me, and Mr. Chairman, you referred to this earlier, when you read the Clean Air Science Advisory Committee's letter with respect to particulate matter 2.5 submitted to Administrator Browner last June 13 that it states, "The deadlines did not allow adequate time to analyze, integrate, interpret and debate the available data on a very complex issue." I think that says a whole bunch.

In regard to public support of public health issues, many municipalities have made Herculean efforts to come into compliance with the NAAQS and Oklahoma City and Tulsa are very proud to say that this State is an attainment State.

But to learn now that instead of some recognition for the accomplishment for these efforts that we find out that the efforts might have been inadequate, inappropriate or ineffective is quite dismaying for those cities that are not in attainment yet, there are those you heard in Ohio, they are working so hard and diligently to get there.

So, if we're being told the investments we've made have proven to be futile taxpayers will not continue to fund these issues if it doesn't mean anything and I hear 5 years from now that, no, these standards weren't good enough.

There are some inconsistencies with other laws, ISTEA was mentioned earlier, and I would like to direct my attention to one issue that as we face more stringent controls on emissions causing air pollution, many of which are generated by stop and go rush hour traffic, we are simultaneously hearing proposals which would cut mass transit operating funds, which provides a virtually guaranteed method of reducing the proximate cause of the pollutants.

Equally seriously, there are those in Congress who in proposing changes to ISTEA would remove the Congestion Mitigation Air Quality program, which I believe is a mistake and I—and this is but one inconsistency in terms of the ISTEA issues and other statutes.

Finally, municipal officials are very concerned about being required to comply with Federal standards where there are few or no tools available to attain such compliance or when there is no body of knowledge on how to achieve compliance given the significant unknowns, where, how much, from what sources.

With respect to particulate matter of 2.5 we're concerned about the deadlines and the consequences of failure to meet them in however many areas may be out of compliance.

Despite Administrator Browner's assurances in her recent testimony before your committee that 70 percent of the potential non-attainment areas can come into compliance with the proposed new standards by using existing technology and strategies, the National League of Cities question the validity of that assumption. Furthermore, we are very concerned about the other 30 percent. We're an organization that represents all the cities and towns in this country, not just a percentage of them.

Recommendations. First, we don't believe the Courts ought to be forcing decisions related to complex scientific matters. We believe Congress should overturn the Court's deadline in order to give EPA and the scientific community adequate time to draw sound scientific conclusions about further reductions in air emissions.

Second, if the Clean Air Act requires EPA to review air pollution standards every 5 years the funding to comply with this requirement should be provided. If these funds were not available because of limited Federal resources or alternative national priorities then this requirement should be changed accordingly.

Third, if indeed as Administrator Browner indicated in your recent hearings, over 200 scientific studies support the need for tighter controls on specific air emissions then EPA has done a poor job of publicizing, explaining or demonstrating the adequacy of the scientific basis for their proposals. We either need more and better science or more and better explanations of the science that exists is valid.

Fourth, the impact of the proposed requirements on existing State implementation plans that have only recently been approved needs to be assessed.

Finally, Mr. Chairman, we need better information about the pervasiveness of PM_{2.5} before proposals are finalized, how many PM_{2.5} non-attainments there are, where they're located, how significant is the problem in these areas. It is difficult to accept the premise that a problem exists for there is little information about where it exists.

Thank you, Mr. Chairman and the committee, for this opportunity to testify today.

Senator INHOFE. Thank you, Mr. Schwartz.

And last on the panel we'll hear from the Honorable Mayor of North Little Rock, AR, Patrick Henry Hays.

Who could vote against a guy with a name like Patrick Henry Hays?

STATEMENT OF HON. PATRICK HENRY HAYS, MAYOR, NORTH LITTLE ROCK, AR

Mr. HAYS. So far, Mr. Chairman, it has worked.

Senator INHOFE. Just kidding.

Mr. HAYS. I was re-elected for a third term last November and I hope that that's something, you know, a total attribute in terms of the public's support.

But I am happy to be here and happy that you have given us an opportunity to come to Oklahoma City.

I want to certainly compliment two of my colleagues, I know Mr. Schwartz and Ms. Savage who I had a chance to work with in local government matters over the last several years, Susan through the U.S. Conference of Mayors and Mark through the National League of Cities.

Also I certainly want to compliment our Senator as I had served in the State Legislature with your colleague in the House side of our State Legislature, Mr. Hutchinson, Tim was certainly an able legislator in the House and we certainly compliment both him and your activities as you go about trying to determine what makes sense for the country.

I am the mayor of the third largest city in Arkansas, North Little Rock, with approximately 65,000 people.

However, I'm here representing Metroplan, which is a council of governments composed of 22 member governments in addition to the Arkansas Highway and Transportation Department along with Central Arkansas Transit, which is our metropolitan transit authority.

We represent over 550,000 residents, the largest area in Arkansas, metropolitan area in Arkansas, with somewhere in the neighborhood of 300,000 jobs that are represented in that area.

And let me posture, although I'm speaking for Metroplan, I certainly want to include Crittenden County and West Memphis in the two areas that at least at present in Arkansas would be challenged by these new regulations.

While particulate matter is still somewhat up in the air, because there literally has been no monitoring, and I've heard these comments by others at the panel, my city is the only area in which ozone monitors occur. We have one monitor at the North Little Rock airport and another in an area that is in close proximity to literally the largest diesel electric locomotive repair facility in the country, Union Pacific has its shop in that area.

As such part of my concern, and I'd like to certainly submit the information that I've provided for the record and it goes into a little bit different direction, or not different direction but additional direction that I want to comment on.

Some of the things that I'm real concerned about is the fairness of the monitoring system. With those two monitors that essentially cover that entire geographic area in Central Arkansas one is located in close proximity to the airport, the other to that diesel repair facility and how accurate, is my concern, that whatever monitoring goes on whether that monitoring is certainly accurate in terms of the reflection that it may have.

I think even with our concern about the ozone limitation we're very concerned about where that's going to lead and what that may do.

I think we all recognize that perception becomes reality and the perception that you are a non-attainment area, not knowing exactly what details may have to go into the formulating of a plan and the implementation of that plan.

As transportation has been the backbone of my community, we begin our history as the end of the line, so to speak, of rail coming from Memphis to St. Louis. And as such, with the confluence of Interstate 30 and I-40 transportation has continued to remain a strong part of our community.

I think I could also mention that West Memphis, as its confluence of 200 State systems also, perhaps, has some of the same problems.

We have been improving over the last several years and I think mainly we think that improvement has been attributed to perhaps mild summers in addition to a turnover of the fleet in terms of the national standards that Detroit has, perhaps, been assisting us with.

So our concern is very strong and it is very valid but there's one other point that I'd like to make as a mayor. We sit here and look to Washington and I think the unfunded mandate legislation, which was adopted, was a compliment to the Congress and recognizing that more and more things are being heaped more and more on our shoulders without the funds to address those problems, clean air, welfare reform.

As I mentioned a little earlier on the plane, the restructuring of the electric industry, clean water, storm water drainage, the solid waste, you know, more and more things are being put on us and I think we all know, as a revolt of the constituencies have occurred a number of times, there doesn't seem to be anybody that's coordinating all these burdens that are being placed on the average Joe in the street, or Jane in the street, as we are trying to be the floor where there are no cracks.

People has talked about welfare reform, how people are going to fall through the cracks. Well, those are the cracks that we have to shore up and receive the quality of life problems that are dealt with as Washington deals with spreading its one cookie cutter size fits all over the country.

And I think without—what I've heard more and more said here is that there appears to be no one that agrees that the standards ought to stay the same. That the proposed standards by EPA are not supported by at least anyone at this table and the comments that I've heard, Mr. Chairman, from your table that no one supports those, and so I guess it's going to be kind of interesting and exciting and comforting, I guess in many respects, to see that this

window of opportunity, as you go back to Washington, either through carrying the big legislative stick or certainly encouraging your colleagues to adopt legislation that would give us some relief in terms of where we might be going, not only with what our topic is here but also look at the overall impact that our citizens are having to face in all of these other areas that are being addressed by the Congress.

I compliment you. I certainly want to thank my Senator for giving me the opportunity in coming here and speaking not only for myself. Mayor Dailey, who was supposed to be here from Little Rock, as many might realize, is dealing with some deaths and severe damage that occurred in his city, so on behalf of all of us from Arkansas, both from the central part of the State as well Crittenden County and West Memphis, we look forward to that window of opportunity, that you are going to carry back on our behalf to Washington, opening in a way that will provide us some relief. Thank you very much.

Senator INHOFE. Thank you, Mayor Hays.

Mayor Savage, in your written testimony you brought up the question the fairness issue, and I'm glad you did. It seems like cities such as Tulsa and Oklahoma City are always required to do more than places like New York and Los Angeles even though those cities will probably never come into compliance with current regulations.

You've cited, and this is, I believe a quote, you said, "The health benefit analysis is based—is the basis for the recommended changes." You also stated that there is, "No definitive knowledge about the precursors to ozone."

Are you suggesting that the science is clear on particulate matter but not on ozone?

Ms. SAVAGE. I would suggest that the science on ozone is more extensive than it is on particulate matter, as this committee knows far better than I, the differences of opinion on the validity of the science has been well documented.

To say, and I think Mayor Hays said it well and Councilman Schwartz said it well, we at the local level are somewhat confused about exactly what it is anyone is trying to accomplish.

In thinking through the purpose of our session here today, it occurred to me from the Conference of Mayors, because we have cities the size of Chicago and Los Angeles who are currently not in attainment, to North Little Rock and Oklahoma City and Tulsa who are in attainment and so we all share the goal of clean air. However, the manner in which we arrive to that goal sometimes may be different.

The point becomes there's a concern about the health of our citizens. There is a concern about the impact of this type of very stringent proposed regulation on our local economies. There is clearly a concern that I try to convey about whose responsibility is this and how do we impose the regulation on the governmental entity to clean the air when you can't really capture what you're trying to clean.

So, I don't want to ramble, Senator, but there is certainly a body of knowledge which—a little bit of which I have seen, that says

there are definite health impact to ozone. The particulate matter we know is much less studied.

Senator INHOFE. Let me ask you just briefly, you heard the question I asked Governor Keating about recruiting industry and of course you had great accomplishments in this area too, one of which is Westinghouse. It's my understanding that Westinghouse in Tulsa is expanding largely because of our attainment status. Would you agree with that?

Ms. SAVAGE. We have been the beneficiary of a recent manufacturing location in Tulsa and the company would not have located there had we been in non-attainment we were told and they were expanding and growing jobs, so we're very fortunate.

Senator INHOFE. Senator Muegge, you commented that you're in the Ag Committee. Well, you know, I've visited extensively with people from the Oklahoma Farmers Union, the Farm Bureau and other groups and they're very much concerned about this. Do you want to make a comment as to how the adoption of these proposals might affect adversely the ag community?

Mr. MUEGGE. Yes, I'm wearing two hats here today, I'll put on my agriculture hat.

As you well know, what happened a year ago we had a severe drought and all across Texas and Kansas and Oklahoma why we had many, many days where we had a lot of particulate matter in the air.

Of course, if this would come at a time to Oklahoma City it could place them in a non-attainment situation immediately and, of course, we would be the cause of that.

There's no way that we can manage our farming operations to deal with this kind of a hazardous situation that occurs naturally in our farming operations, particularly when we're at the vagaries of nature. So this is—would place a heavy burden upon not only those of us out in the country that are trying to make a living struggling with agriculture, we could impact cities as well.

Senator INHOFE. You know, coming over here we came over in a small plane, I had a couple of staff people with me and I pointed down right outside of Bristow where a farmer was out in his field and just looking at that we take for granted a lot of the freedoms that we have today and yet we have been told of kinds of stories as to what regulations would go into, particularly in the ag community, and there is a great concern. It really isn't talked about as much as it should be.

Mr. Schwartz, it was kind of interesting, you brought out the 70 percent and the 30 percent. Tell us a little bit more about what would be expected of the 30 percent.

Mr. SCHWARTZ. Well, I think the real problem, Mr. Chairman, is those 30 percent are never going to get there from Point A to B anyhow. I mean the reality is there if you can't meet today's standards the likelihood of meeting under the proposed standards is probably next to impossible.

If anything, you know, there are—there have been, interestingly enough, the variations provided under the act for ozone in terms of under severity of issues, but that, of course, does not apply to particulate matter so you've got whole other world to deal with.

I think you're looking at cities that probably see receding economic development because what—they're going to flee, and that has been the issue, that they have gone from areas where they couldn't get those credits for air emissions and they go to other areas of the country and putting everybody across a level playing field where nobody can have economic development does not help the country in terms of a global economy.

Senator INHOFE. Mayor Hays, you brought up in your written testimony the effect on ISTEA and I've commented several times I have a great deal of respect for Rodney Slater, I know you know him well, and when he was testifying before us he really wasn't clear as to what types in a budget request of money should be requested because everything is so ambiguous right now.

Would you have any advice for Secretary Slater on what he should ask for in terms of an appropriation to take care of this contingency?

Mr. HAYS. Mr. Chairman, I always would have advice for a cabinet member, now whether or not it would be any that he might take I don't know, but the whole gamut of what we're trying to do here is to try to improve the health of our citizens.

Without reliable information, I think Governor Keating, if I remember correctly, commented about how can you do anything other than try to make sense and it doesn't make any sense to go forward in trying to develop plans to spend resources to scare literally new employers from either bringing their companies into your area or adding to their work force unless you have some reliable data to act on. I think that's one of the biggest concerns that we all have right now that that's just an impossibility.

Senator INHOFE. It is. My time is up. Let me just ask you a yes or no question, we'll start with you, Mayor Hays, and just run down the table.

Would you consider if these proposed standards went into effect to be an unfunded mandate?

Mr. HAYS. Yes, I would.

Senator INHOFE. Mr. Schwartz.

Mr. SCHWARTZ. Most likely it would be.

Ms. SAVAGE. Yes.

Mr. MUEGGE. Yes.

Senator INHOFE. Thank you very much. Senator Thomas.

Senator THOMAS. Thank you. Let me read you something. This is not an unfunded mandate but is very similar. This is a letter from the Assistant Administrator. As you know, new and revised NAAQS are based on air quality criteria issued under section 8 of the Act set at levels sufficient to protect public health and public welfare from the adverse effects. Once the standard is set or revised the States are primarily responsible for ensuring attainment and maintenance of it under section 110 and part of the States develop and States implement plans covering under this framework the potential or revised standard if adopted would not establish any requirements. Therefore, the rulemaking is not susceptible to regulatory flexibility or unfunded mandates as prescribed. They establish no requirements applicable to small entities.

So, what they say is that the standard does not do it it's the States implementing that causes it and so that's a fun thing to live with.

At any rate, we'll expect you guys from Arkansas to do a great deal with this.

Mr. HAYS. We'll be happy to carry the load Senator.

Senator THOMAS. I don't quite understand, Mayor Savage, you talked about the cities activity. This is transferred to the State to implement, is it not, what is the legal statutory responsibility of the city?

Ms. SAVAGE. Senator, were you referencing the comment I made regarding our flexible attainment region, our FAR agreement that we've negotiated with the EPA?

Senator THOMAS. Not particularly but you talk about the things that you have to do with the city. What is that a result of, the State's implementation program?

Ms. SAVAGE. It's a combination things. We went several years ago to the Environmental Protection Agency because Tulsa has been be in attainment since 1990.

Subsequent to that and because of our ozone alert program, which has been modeled by cities across the country, we went to the EPA to say, wait just a minute, we're doing these activities, industry is producing gasoline which has a lower re-vapor pressure voluntarily. We're paying for free bus rides on days with a high ozone alert or probably exceeding our standard, we're doing that voluntarily as a community yet we receive no credit. Communities in non-attainment who are working toward attainment who do the same things receive credit. We need to be in balance here. We need the same credit.

We negotiated a flexible attainment region agreement with the EPA, with our State Department of Environmental Quality, with our Chamber of Commerce, with our metropolitan planning organization, with the city of Tulsa, with Tulsa County, to give us a framework in which we would say if Tulsa exceeds the number of allowed occurrences within a set period of time then we will agree to do—and it's prescriptive, a variety of different things.

We went to the State legislature last year and passed a gas tax—or excuse me, a gas cap law that would require if we violate the standards for us to, as communities, to be able to implement a more stringent type of gasoline cap.

Now, I use that way of example because Oklahoma City has negotiated a FAR agreement that's a little bit different. It allows a community to work with the State organization, with the business community and with the Federal Government in a partnership model to address any environmental concerns.

It makes sense. It enables to us to really be the guides of our own destiny and to continue to be responsive in trying to clean up the air.

Senator THOMAS. The State has the primacy, does it not, in Oklahoma to enforce these—

Ms. SAVAGE. Yes, there's a State implementation plan and they are partners.

Senator THOMAS. So, do you measure by cities? The city is not the unit that you measure, is it?

Ms. SAVAGE. Well, it's on a county basis.

Senator THOMAS. You do it by counties or—

Ms. SAVAGE. It's a county basis. The Tulsa area, our council of government's area is comprised of five different counties, now they're not all members of this agreement.

So the point becomes, it's kind of complicated to explain, but it is a way to take the goal of cleaner air and to make everybody responsible for that occurrence.

Senator THOMAS. You were talking about monitoring equipment, I think, Mayor. Do the cities do their own monitoring?

Ms. SAVAGE. City-County Health.

Mr. HAYS. In Arkansas we don't. The Department of Pollution Control and Ecology, if I'm not mistaken, is the one that has monitoring authority.

Senator THOMAS. State entity?

Mr. HAYS. That's correct, that's a State agency.

Senator THOMAS. And that's true also in Oklahoma?

Ms. SAVAGE. City-County Health Department. City-County Health Departments do it. We also have issues of the placement of our stations. We exceed often—not often, but when we do exceed it's most likely near our airports.

Senator INHOFE. Let me interrupt just a minute. We're in kind of an unusual situation. In Tulsa our city and county lines are very close to the same.

Senator THOMAS. I see. Well, you should move that one away from the airport.

Ms. SAVAGE. Well, we thought about big fans out there on days when the air doesn't move and I made the statement earlier that, you know, we don't feel we have a serious air problem in Tulsa it's a weather problem. Typically, and the Senator knows this, on days where there's high humidity, no wind, it captures the particulate matter and the ozone in the air and it doesn't disperse.

We have issues of transport, which is another concern of cities like Oklahoma City and Tulsa. We started our southern most monitoring station on ozone—high ozone risk days many times at .05. Well, we're already well on our way to the top level of the standard.

So, we have a lot of issues and I make the point again, we all want clean air but there are more questions than there are answers today in what has been proposed.

Senator THOMAS. So, if I understand it correctly—well, let me ask you this very briefly, what would you like to see happen, are you for withdrawing these, are you for more time, do you have—the legislatures or municipalities, do you have a suggestion, in a sentence what would you do?

Mr. SCHWARTZ. The National League of Cities is very definite in its resolution that Congress override these proposed regulations and then take the appropriate time to study and if there are appreciable health benefits find a reasonable way to do it but we don't know that yet.

Ms. SAVAGE. The Conference of Mayors would concur with that general approach and add to it that as we discuss environmental issues we need to look at Federal coordination among some of these policy issues.

How are we going to clean up the air and address transportation because, you know, I mentioned urban sprawl and it has happened for us, and part of that involves the cutbacks in areas of public transit. So some of those policy goals need to be examined and better coordinated.

Mr. HAYS. We, in our metropolitan area within the framework of what EPA is considering, very briefly, we supported the AR concentration basis standard because we felt it was more aggressively associated with the reality of the problems. The conventional rounding method where they round down, we support retention of that.

We do not support their average third highest daily maximum set at eight parts per million. We believe the 8-hour ozone standard would afford protection over the current standard for persons at risk either at the third highest daily set at 0.09 parts per million or the fifth highest set at 0.08 parts per million was the recommendation that comes from our Council of Government.

So, essentially, I think over all we're hopeful that there's little or no change unless there is—absent scientific information, but if there is within the parameters those are our recommendations.

Senator THOMAS. Legislature.

Mr. MUEGGE. Presently, probably as we speak, why the Senate should have passed on a concurrent resolution with the House to request that these proposed rules be delayed and a further study be considered.

Senator THOMAS. Thank you, sir.

Ms. SAVAGE. I will offer, Senator, one point that I think you will find occurring among the municipalities and local governments, and Mayor Hays referenced it as the 8 hour averaging. I think these hour readings where you have a spike in the afternoon and potentially it exceeds and violates the air quality standards because of what happens between 2 p.m. and 3 p.m. seems to be a little silly.

Senator THOMAS. Sure. Thank you.

Senator INHOFE. Thank you. Senator Muegge, I'd like to ask you to submit for the record the resolution as it is worded and the votes, how it comes out too.

Mr. MUEGGE. I will take care of that.

Senator INHOFE. Senator Hutchinson.

Senator HUTCHINSON. Thank you, Mr. Chairman. And I thank the panel for your contribution.

I especially want to welcome Mayor Hays, who I had the opportunity to serve with in the Arkansas legislature and I'm glad to get to visit with my colleague again and we appreciate your testimony.

And also, Mr. Chairman, I would like to acknowledge the presence of Mr. Allen McVey, who is representing Governor Huckabee from Arkansas, and Becky Keogh, who is with the Department of Pollution Control and Ecology, who is representing the State of Arkansas as well today.

I would ask unanimous consent to have entered into the record a letter from Governor Huckabee to Carol Browner asking for delay in implementation of these proposed rules.

Senator INHOFE. Without objection.

Senator HUTCHINSON. And a resolution from the Arkansas House of Representatives asking also that until further scientific health science data is available that those standards be delayed.

Senator INHOFE. Without objection.

Senator HUTCHINSON. I'm going to hand—let me hand them to you in just a moment, Mr. Chairman, but in Governor Huckabee's letter, Mr. Schwartz, I want to ask—I want to read this and then ask you to respond to it.

Environmental Protection Agency, he writes, has identified one area in Arkansas, Crittenden County, as an area of possibly subject to redesignation to non-attainment with revised ozone standards.

The case of Crittenden County, which is West Memphis, AR, the ozone levels are primarily due to the proximity to Memphis, TN, and a large number of transportation vehicles which travel along the interstate highway corridors through the area.

Control of emissions from the primary sources are not possible within the areas to be designated. Expensive local control agents will have marginal to no gain in air quality somehow multi-state sources can be addressed under the proposed rule.

I don't know who I want to toss that out to but it would seem to me that in border cities, where clearly in this case where you have a smaller urban area like West Memphis, AR, adjacent to a large metropolitan area like Memphis, TN, and where it's clear that the—being out of attainment is primarily because of—it mentions in another area that no matter what they do in West Memphis they're still going to be out attainment.

How does the proposed rules suggest that be handled?

Mr. SCHWARTZ. Well, Mr. Chairman and members, Senator, I tell you, I find it real frustrating in terms of the ability for me—to put me in a position where I might have to, or West Memphis, may have to go and start suing one another under regulations because it came from here.

I think part of the difficulty, as Senator Muegge has said, not all the council and State legislators have made up their mind yet in terms of where this rule should go.

NLC has but I know that the Governors are split on both sides of the issue, on both sides of the aisle that is, Republicans and Democrats have different positions on this depending upon where you are. It is a very regional issue.

To put people in the position where we can go to the government and say, my friend Pat here is a good friend but, Mayor, I'm sorry, we're going to be suing you because you're sending over. Well—or we are sending to you. It makes it very difficult particularly when there are other methods to do things.

Now, down in this part of the country, as you well know, we can drive cars more than we have mass transit. However, we have made great strides in terms of mass transit in Oklahoma City and in Tulsa and other regional areas, not to the extent of subways in the major cities, but I would suggest that we need to keep enhancing those issues. We have done that in Oklahoma City and Tulsa with the use of compressed natural gas in our buses instead of all being diesel, which contributes to those pollutants.

I think it is terrible to put areas, regions, cities, and States to fight one another. I think it is a mistake to do that and it only

opens up the door to greater frustration and Washington is going to be saying, go out there, children, and settle this amongst yourselves.

Senator HUTCHINSON. This proposed rule really invites more of that?

Mr. SCHWARTZ. Absolutely.

Ms. SAVAGE. It also misses the point. I think we have substantial issues. Transport, we know they're real but it doesn't get us to how we address that, it just puts us in a fight with one another, which is not productive. So, just to listen to what you've described, I would say it substantially misses the point.

Mr. HAYS. Senator, if I could add one point. We had a meeting in Executive Committee of the Arkansas Municipal League last week and one of the issues that came up there's legislation or a bill that was filed to remove the authority to prohibit open burning, the back yard type of burning by DPC&E.

I spoke against that legislation because it would add—potentially add particulates to the air. One of the smaller mayors in Arkansas came up and said, well, I'm kind of angry at this body because, you know, you all always run over us when it's a rural or urban issue and the discussion went around to the fact that we just really didn't think that all of us understood that because, for example, if this legislation—or this rule is made firm and we became non-attainment, it's my understanding that there's a 60 mile radius around the area of non-attainment that would govern it and if you look at Crittenden County and look at Pulaski County, you're literally looking at everything up and down I-40 from, you know, Little Rock, North Little Rock to Memphis and that encompasses a large rural area, as I know the Senator is aware.

So, you know, in many instances, although it seems to pit one against the other, whether it be geography and States or whether it be urban versus rural that is not the case. There would be a lot of rural area that would be encompassed particularly as Arkansas is somewhat of a State in a geographic square, more or less, and the amount of territory that that would take up in Arkansas. So, we've got a lot of educating to do. I don't think that the general public is aware of what lurks out there.

Senator HUTCHINSON. Mayor Hays, while you're talking I have a threefold question. You in your testimony addressed the issue of ISTEAFUNDING and how that might be impacted and I would like you to speak to that, the investment in job creation, a problem of this rule, what it will do to States like Arkansas.

And, third, I had a letter from a company that serves Arkansas concerning electric rates and the impact. I know that North Little Rock has municipal power but this company estimated that electric rates would go up 8 percent to the residential customer in order to comply with these new standards.

What would it do, do you have any idea what it would do in North Little Rock?

Mr. HAYS. Let me just try to be very brief. I know ISTEAFUNDING has been addressed with somewhat of a question mark, although certainly significant increases in the cost.

There's one other aspect that I'd like to point out and that is if there is a non-attainment area within the State some funds that

have a quasi label to them that are currently going to the, for example, the Arkansas Highway and Transportation Department, \$5,000,000 to be precise, would have to be redirected toward those non-attainment areas, specifically programs that would address the ability to attain or reach an attainment status.

So, whereas there is some discretion within, at least as our State goes, the Arkansas Highway and Transportation Department, not only would the cost accelerate but also some of the funds that are currently being allocated would have to be reallocated within the distribution formula to—

Senator HUTCHINSON. But it's five million that is currently going into road construction that would be diverted into mitigation?

Mr. HAYS. Could be. Could very well be. You have to be in compliance with the plan that would then be developed in order to try to address the non-attainment status so it would be—

Well, and I'll give you a partial example that, you know, some of those discretionary funds could go toward completing 71 up in the northwest part of our State and now they have to be directed toward Crittenden County or central Arkansas in order to meet our non-attainment status.

You know, whether that would be a valid effort to attain it or not, again, is certainly up to this body as well as EPA.

Job reduction, as I mentioned a little earlier. North Little Rock, Central Arkansas, in the confluence of transportation, with both water, Mayor Savage and I are on an informal committee of the Arkansas River navigation communities and are very proud of that transportation thoroughfare that Senator McClellan, along with Senator Kerr, I believe of this State, helped complete. But to try to be brief, transportation is really the life blood—or strong life blood of our area. And to the extent that companies would relocate or not locate or not increase could be very vital to the economic wellbeing.

We've been at 3.5 percent unemployment for a number of—well, 3 years plus. We can see this certainly as a wet blanket that would be thrown around that.

Electric rates, you know, the cost of doing business there are no small numbers in utilities, particularly electricity, the livelihood of companies that come into your area. Wright Video, which is one of the largest production facilities that has come to Central Arkansas, almost a thousand employees now and growing, their key cost ingredient is electricity. Anything that would affect that would affect their livelihood and as such so would our livelihood be affected. So, the impact would be catastrophic if reasons didn't meet the road in an appropriate way.

Senator THOMAS. Could I just be a Devil's advocate for a minute?

When you talk about jobs and investment are you talking about world competition or if everyone in the country is covered by the same thing what difference would it make?

Mr. HAYS. Senator, I think we all realize now that we no longer compete with—I know northwest Arkansas and central Arkansas used to be at each other's odds in trying to divide up the legislative pie. I think we more realize now that we are competing with economic regions, whether they cross State boundaries or national boundaries, and literally we are—we're not competing so much as

a nation anymore—I mean as a State or city as we are with those regional economic areas but worldwide.

More and more that worldwide competition, you know, is going to be between central Arkansas and central South Africa so we can't say that we can roll up our borders and go home anymore. I think that's just being naive.

Senator THOMAS. I don't want to be confused, I'm not for that either, but I hear that question, you know, they say, well, you're going to treat everybody equally bad what difference does it make.

Ms. SAVAGE. I would add to what Mayor Hays has said is that as we are different regions of the country we have different air quality issues with which we must address and I think a standard that applies uniformly to everyone across the country doesn't make any sense.

Senator INHOFE. Thank you, Senator Hutchinson.

Senator Sessions.

Senator SESSIONS. Thank you. Mr. Chairman, I'm delighted that you chose to have this meeting in Oklahoma. I thought maybe it was a parochial interest but—and I know we have two good Senators here, but look at the leadership that you've put together here.

We have Mayor Savage and she is on the Environment Committee of the U.S. Conference of Mayors and is speaking for them. You have Oklahoma City Councilman, Mr. Schwartz, president of the National League of Cities. We have Mr. Hays, who represents 22 governmental agencies. And Mr. Muegge is speaking for and on behalf of the National Conference of State Legislatures. This is a remarkable group you've assembled and it is, I think, as public policy centers, remarkable that—and the Governors we had previously are all very troubled by these regulations and I think we have to raise questions.

I also note among Oklahomans my legislative director, Rick Derwin, is an Oklahoman. I don't know if his parents are here. Are they here? They might be. Rick is a dynamo and I wish he could have been with us today.

So, I'm impressed with the backgrounds and I'm impressed with the unanimity of the concern. I think any of us who have the ability to pass laws or control the imposition of regulations that can cause billions and billions of dollars of costs need to be listening to the people who do that.

One of the things that was interesting to me, last week I had occasion to have dinner with three of Jefferson County, that's Birmingham, Alabama primarily, of county commissioners and they were talking about they were endeavoring to get out and reach attainment under the old standards.

They made remarkable progress, Birmingham has over the years, just tremendous progress. It used to be so bad but it's just almost in attainment now. They talk about—they were considering reformulating gasoline.

Have any of you considered that and have you learned that that may be not only not a benefit but a detriment?

Ms. SAVAGE. Senator, we do it. In Tulsa our industries do it as part of our ozone alert effort. They do it voluntarily. They do it understanding that there's no incentive from a cost standpoint to do it. It is just good public policy to keep Tulsa in attainment.

They voluntarily each year have lowered the re-vapor pressure of the gasoline produced and sold in Tulsa so that we—because 70 percent of our ozone problem relates to hydrocarbon emissions from automobiles then to sell a product with a lower re-vapor pressure helps to address that, they've done that voluntarily.

And I—while at the start of my formal comments I did not have time to say I think one of the strategies, perhaps, that would be of tremendous benefit to communities and to industry is to work from an incentive based approach rather than a punitive approach because I think those industries who have stepped forward in Tulsa to say we understand air quality is our concern, there's a business cost to it. While we don't have any—there's no business benefit in the short term. In the long term we all benefit from cleaner air. So we've done it. We do it on an annual basis. We stay in attainment because of the industrial support that we have from our community.

Senator SESSIONS. Well, I think that was encouraged by EPA and was a source of real encouragement but recent reports, including a pretty in-depth article in the Wall Street Journal has indicated that reformulated gasolines produces formaldehyde in the atmosphere.

We've had a number of health complaints about people who breathe the fumes and my county commissioners were saying I wish EPA would tell us whether that really would help or not. I hate to commit to a program and then find out it's really not productive.

Ms. SAVAGE. I probably need to correct something. When you say reformulated gasoline I jumped right into lower re-vapor pressure and I know those are two different things but the point becomes we are trying a variety of strategies voluntarily to see what works.

We all keep coming back to the same point of discussion here that the science is still pretty new in terms of the technologies which can help us.

We're all for more research and more innovative technology and will work with the Federal Government to explore different options because I think that's to our benefit to do so. So, it does get frustrating.

I think you hear some of that here because we're trying to stay within this arbitrary set of regulations yet we don't exactly know what works the best. I mean if everyone goes in their house and stays inside we're probably going to be OK on those poor days but that's not very practical either.

Mr. SCHWARTZ. Senator Sessions, I might—and I guess Oklahoma City could be in a position from say, well, OK, we currently clean our streets with street sweepers because it helps us. One, it's a livable city issue, but it also avoids issues when you get the storm water runoff, which helps us there. Now, if I've got street sweepers out there it's going to kick up all this particulate matter.

You take the street sweepers, take the landfills in this country and every day, under EPA rules, daily cover has to take place at landfills. PM₁₀ does apply I think currently to the landfills but it would go to 2.5 and somehow the rules always get over to air quality standards as well, building roads, et cetera, et cetera.

In essence, you know, we've got Washington who tells my colleagues in the State what to do, and the State and Washington tells us what to do and we have no one else but the taxpayers. There's only, as you all are debating and discovering in Washington, there's only so much money. There's only so much money and I think we need to make sure that we use our taxpayer's money as wisely as we can.

To put us in a position where we start conflicting with other laws that we have to comply with, such as storm water runoff, you know, you've got to understand the vast majority of local officials who will become very educated and are very dedicated people, out of the 16,000 in this country most of us make next to nothing and do it as a volunteer and the issue is you've got educated people who are trying to work hard because the burden has become incredible. When the Unfunded Mandate Bill was passed NCL supported it and so everybody passed it and they kept on sponsoring that. Where are you going to put us?

You know, it reaches a point where people are just going to throw their hands up in the air when there's no science and no appreciable benefit.

Senator SESSIONS. One of the things you mentioned about dust. Scientific American had an article I read just by chance earlier this year, and it analyzed particulate matter and acid rain and what it discovered was the 1990 Clean Air Act, which has done some great things, has reduced particulate matter but the particulate matter from burning and the other things act as a base and tends to neutralize acid rain. We've gotten little or no improvement in the acid rain, in some areas perhaps worse, because there's a—and so there's a doctrine of unintended consequences that we have to keep in mind and that's why good science is crucial.

We don't know whether one particulate—maybe it's the particles from burning of leaves that causes the problem and not the particles from diesel, gasoline, or vice versa. We have no idea which particle it is that may be causing the health—and I think it is important to note that none of the ozone or particulate studies that we've seen indicate that these are carcinogens and none indicate that they are damaging, so far as I understand, to healthy individuals but can exacerbate health conditions in those who are sensitive to matters. So, we just need to know what we're dealing with I think.

I would only make one more point to confirm what you're saying. It looks to me like we have a county of 13,000 about 50 miles from Birmingham that's out of compliance with about 13,000 people or so and it's because of Jefferson County, Birmingham, and nothing that they could ever do is going to get that county in compliance.

Senator INHOFE. Thank you, Senator Sessions. We have time for a second line of questioning if it's brief, and we'll adhere to 2 minutes.

During our hearing in Washington when Carol Browner was there she talked about the fact that it would take between 3 to 5 years to really analyze and determine which PM's would be—the real villains here and another 3 to 5 years to designate non-attainment areas.

Of course, CASAC, the scientific group testified in their hearing that it would be 5 years before we really know which, if any, of the PM's and at which level were hazardous to the health or to respiratory illness.

I'm going to read the resolves that Senator Hutchinson mentioned that was passed by the Arkansas State Legislature then I'll ask each one of you just kind of yes or no do you agree with it starting with Mayor Hays.

Be it resolved that due to remaining uncertainties and the lack of causality between PM_{2.5} and adverse health effects that EPA should abandon its current consideration of PM_{2.5} standard until more information, including sound science and cost effectiveness data are available.

Mayor Hays.

Mr. HAYS. Very briefly. Yes, to that answer and on both of the resolutions that I brought, not only from my city, which is attached to my testimony, as well as the resolution adopted by the Metroplan, the Council of Governors both speak to that issue, agree with the Arkansas Legislature and I think you could probably safely say that there's unanimity at least in all three of those, those two bodies that I represent with the Arkansas—

Senator INHOFE. I was asking this question really in your capacity as an elected official as opposed to standing for it in an organization.

Mr. HAYS. Absolutely.

Senator INHOFE. Mr. Schwartz.

Mr. SCHWARTZ. I concur, yes, sir.

Senator INHOFE. Mayor.

Ms. SAVAGE. Yes.

Mr. MUEGGE. I would concur. I would like to make a remark, Senator Inhofe. I think that in our Nation what we've done in the past is we've always identified a problem and a crisis and we've attacked that with vigor. We had unlimited resources and we ran out there and solved that problem.

I don't think we're going to have those kind of resources anymore. I think what we've got to do is look at any issue comprehensively and make sure we know what the consequences are and understand from the very beginning that we can't resolve all of the problems, all of the issues that we have facing us, particularly government can't do that. So, I think that's a new order that we need to very seriously look at and make sure that our citizens understand what the costs are and what the benefits are.

Senator INHOFE. Thank you very much.

Senator Thomas, do you have any remaining questions?

Senator THOMAS. Just I guess I would like to say, I'm looking to you, Mayor, how do we—how would you handle this business of having uniform standards?

I think you objected to the idea that you applied the standards everywhere.

Ms. SAVAGE. Well, if I were in charge of writing the standard—

Senator THOMAS. Let's pretend you are.

Ms. SAVAGE. I would promulgate standards in a general way and then work with, on a regional basis, to address specific concerns. We know in our area for the air quality problems we have what

they are. We have some ideas about how to address them and we do a number of things.

But I think if you talk to any community or any region you will hear essentially the same thing, that I don't want to be held to the same standard that Chicago is, for example, because we have very, very different environmental issues.

So, I would seek a formula. I don't presume to offer one, I'm sorry, but I'll work on that, Senator, that is—that provides a way in which we have the flexibility but we're also asked to perform, to demonstrate, to create innovative solutions which we can use within—in partnership with governments and business.

So I think the standards sometimes get—we get hung up in the numbers and they seem to be rather arbitrary.

Senator THOMAS. That's kind of the pattern of central government, I'm afraid.

Mr. HAYS. Senator, if I could, briefly, you know, and this may sound a little bit radical, but I would have no standards but what I would do from a congressional standpoint is focus as much energy and resources that I could toward research and understanding of what the problem is and to that extent I would publicize that information, you know, as the local community, then it would be my responsibility to decide along—I say mine, it's not individually but certainly as a community, to decide how we could address that.

Public safety is one that we took a real leadership role in Arkansas. That was something that was threatening the health and safety of our community as it is certainly in many areas nationwide. We took very active and aggressive steps to reach that.

If we understand what the problems are, those of us that are local officials, along with those who live in our community have been—have been very proactive in trying to address those. Again, I think what we've found here and continuing to find is that we don't really know how serious, if we have a problem, and if so how serious it is.

Senator INHOFE. Senator Hutchinson.

Senator HUTCHINSON. Just following up on what Mayor Hays said. If we could take all of the resources that will be necessary to enforce these new proposed standards and apply that to the kind of research to obtain the data to answer the kind of questions that Senator Sessions asked a minute ago about causality. I think if we're really concerned about the health and safety of boys and girls in the United States that would be far more productive use of our limited resources.

Just to touch base, Mayor Savage, I think you said Tulsa doesn't have an ozone problem they've got a weather problem. I kind of like that.

Ms. SAVAGE. Well, I'm the mayor.

Senator HUTCHINSON. There were two studies found that if we control all man made volatile organic compounds, one of the components necessary to create ozone, that still there will be natural phenomena which will raise areas out of attainment for ozone. So, even Mother Nature cannot comply with the EPA if in fact that's the case.

So, do you have any suggestions? I think Senator Thomas was pretty much on target, that if we could find the kind of flexibility,

find a means of providing the flexibility for local governments and for States without the one-size-fits-all and the kind of regional differences that we will have gone a long ways.

Ms. SAVAGE. I would maybe summarize what my colleagues here have said, that we're all concerned about air quality. We want to work toward cleaner air. We want to do that in a manner that fits our communities.

I think increasing our flexibility, being able to average the measurements over an extended period of time rather than arbitrary measurements on an hourly basis makes some sense.

Having the opportunity to really extend the ability to have more research in this area that some technology which actually may make sense for communities and for business to me seems a tremendously good investment.

So, as we all work toward this, the message from the mayors would be don't hit us so hard that we can't get up again and give us the flexibility, give us an opportunity to work together on these kinds of things and I think you're going to find we'll be pretty successful at it.

Senator HUTCHINSON. Mr. Chairman, if I could ask one other thing. I think I heard Mayor Hays and I think Mayor Savage also that one of the problems was the location of these monitoring. How is that determined? We've got them at an airport. We've got it by a diesel—how are those monitors—

Mr. HAYS. I just found out yesterday, or day before yesterday, Senator, where mine were located. For a county they're both in my city, exactly where, DCP&E made that selection, and so the burden of the entire central part of the Arkansas rests on my city's shoulders and I'm not sure exactly why that is done.

Ms. SAVAGE. I think you're going to hear from some State folks here, you can ask them that question, they're the ones who do that.

Senator HUTCHINSON. I will do that. Thank you very much.

Mr. HAYS. Senator, may I ask, was the written testimony, Mr. Chairman, that we have submitted, was that all of which made a part of this record?

Senator INHOFE. Yes. Your entire statement will be submitted and will be a part of the record and will be used.

Senator SESSIONS, do you have any further questions?

Senator SESSIONS. I will just ask if anyone would want to comment on the concern that it places us in the competitive world market. Do you know of any companies, we have a lot of paper companies in Alabama, for example, they also have plants all over the world, they're building them in South America, in Canada, and places like that.

If we are—do you think that these regulations strictly enforced when other nations are not enforcing such regulations will continue to drive American industry at even faster rates out of our country to other countries?

Mr. HAYS. Just a quick observation. I think that—and, again, I want to come back to the scientific data. I think that if we have some clear evidence that a certain level of ozone or a certain level of particulate are adversely effecting the health of our citizens, then I think that's the responsibility that we want to shoulder.

Senator SESSIONS. I agree 100 percent.

Mr. HAYS. So, regardless of whether that puts us at a disadvantage internationally is something that I'm going to try to support and do all I can to see that it's achieved.

It comes back to that line of what is adversely affecting the health and safety of those citizens that I'm responsible for.

Ms. SAVAGE. Senator, I would add to that by saying, and Senator Inhofe made a reference to Whirlpool, but we also have Hiltie Corporation, which is an international company who has a presence in Tulsa. Loughton, which is an international corporation which has a presence in Tulsa. Both of whom are undertaking or recently have undertaken expansions in our community, both of whom went two or three steps beyond what they needed to do under existing environmental regulations, they just felt it was the responsible thing to do.

I'd like to be able to—and we can do it on a community leadership basis, to say these are great companies, look what they're doing, they're helping to clean up our environment, but there are a whole bunch who aren't as well and I think there needs to be some way to, perhaps, hammer on some of those offenders but overall I think our approach has been more punitive and it should be just in the policies overall. I would like to see us move to more of an incentive base for communities who really are working with their businesses to clean up the environment, cleanup the air, cleanup the water, provide for environmental mitigation as well as job growth. I think the two are very compatible and we ought to be developing policies that would support that.

Senator SESSIONS. I'll just say that this panel today, we've focussed primarily on the question of what the implementation burden would be, we're asking you who will be there. We've had committee hearings on science and health and we need to do some more. I think it is—science at this point on health questions are inconclusive. But it is—I think it's appropriate that we do consider what you will have to go through if these regulations go forward.

Ms. SAVAGE. Thank you.

Senator INHOFE. Thank you, Senator Sessions.

I want to extend to each one of you our appreciation for coming today and spending so much time with us.

It is very meaningful and it's kind of nice when you get out of Washington you talk to real people and you find out what real people are thinking.

Thank you very much.

Ms. SAVAGE. Thank you, Senator.

Mr. HAYS. We know that that window of opportunity will be opened and that a breath of fresh air will blow back to Washington.

Senator INHOFE. Good for you. Patrick Henry Hays, thank you.

Before the next panel comes up, it will be our final panel, that will leave 1 hour for that panel. We're going to take a 5-minute break for any reason and look forward to introducing the next panel.

[Recess.]

Senator INHOFE. We'll now introduce our last panel. Our last panel is from some surrounding States. We have Dr. Ron Hamerschmidt, director of the Kansas Department of Health and Environment. I will make a statement, since all of you are wondering, he's

not related to any of the Arkansas Hammerschmidts; Barry McBee, chairman of the Texas Natural Resource Conservation Commission. Gus Von—help me with that.

Mr. VON BODUNGEN. Von Bodungen.

Senator INHOFE. All right. He is here from the State of Louisiana Department of Environmental Quality. I have to say that I shared with him the experience that we had when our Super Fund clean-up was taking place in his hometown of Baton Rouge, it was when Oxy U.S.A had the spill, and they had a plan to do it in about 2 years and the EPA came in and said, no, we want to do it under our supervision, which would have been about 9 years, I think we ultimately prevailed on that.

We also will hear from Richard Grusnick, deputy director of the Alabama Department of Environmental Management.

We will be adhering to a 5-minute rule on opening statements. Your entire statement will be submitted to the record and we'll start over here with Dr. Hammerschmidt.

**STATEMENT OF RON HAMMERSCHMIDT, DIRECTOR, KANSAS
DEPARTMENT OF HEALTH AND ENVIRONMENT**

Mr. HAMMERSCHMIDT. Thank you, Mr. Chairman and members of the committee.

I'm happy to be here today to provide you with some comments on the standards.

Our department has a critical interest in the proposals for these standards because we serve a dual role.

We're both responsible for developing and implementing state-wide protection programs and with public health and we're also the implementing agency for these rules as they're proposed.

On this basis we're going to talk today primarily, however, about implementing perspective of our agency and not get in too much of the health effects research.

The State of Kansas is proud of our air quality and recognizes the importance of clean air to the health of our citizens, its environment and its economy.

Kansas is currently in attainment for all ambient air quality standards statewide. Our past successes can be attributed to the ability of local, State, and even Federal Government agencies across our State to work effectively with the affected business interests, special interest groups, and the general public. These relationships are critical to any success that we might have.

Although many questions remain relative to technical requirements and implementation costs, our fundamental concerns lie in two areas.

The first is the shortage of information and apparent inconsistencies in that information about the particulate 2.5 standard. The particles of greatest concern in the 2.5 that are being distinguished from the coarse particles currently regulated is based upon their characteristic differences, i.e., they're combustion related, they might be soluble chemicals, chemically reactive, et cetera, and that they originate from different sources than the secondary—the larger particulate.

However, information as to the source of the PM_{2.5} indicates that there is a significant overlap between fine and coarse fractions in

the many sources of fugitive dust, which includes paved roads, unpaved roads and windblown dust that you've heard about today.

This confusion is exacerbated by lack of 2.5 data in rural States. As a result, we think the fugitive dust component of $PM_{2.5}$ emissions in rural States may represent a source of exposure that's not intended to be implicated as a target of concern by the health studies completed in primarily the larger urban areas of our State of the United States.

It is apparent to us that adequate study has not been completed of any of these sources in rural areas. Because of our concerns we will be providing additional comments.

Our second major area of concern involves the potential impact of the proposed revisions to the ozone standards on primarily Kansas City.

Historically, ozone has been a concern in the metropolitan area. This is a five county area that goes across State lines, two counties in Kansas and three counties in Missouri.

It was declared non-attainment in the late 1970's and remained as such until 1992 when we managed to achieve attainment status with a redesignation.

In order to gain that status two States of Kansas and Missouri were required to demonstrate compliance with the existing standards.

I would note that that has been a joint effort between the two States, between the local municipal governments, between local county governments and also the Mid-America Regional Council, which is a forum for determining how we can best work on these issues together.

We had a violation in 1995 at, of course, one of our stations located by an airport, as everybody seems to. These exceedances have resulted in a violation and we have been working in recent months through an organized local regional air quality forum consisting of a broad coalition to come up with a way to avoid further violation and maintain our attainment status.

They have made a number of recommendations related to emission control, transportation management and air related public education compounds in the Kansas City area. Forum members have arrived at a fairly clear consensus.

As you might well expect, we are also working some resolutions through our legislature and will be happy to provide those to the committee when they're finally adopted.

State and local governments are also currently reviewing plans based upon this air quality forum's recommendation.

Although we continue to progress in the Kansas City area under our current plans, the proposed revision of the .08 parts per million would result in a return of our Kansas City area to non-attainment status and we would have to deal with our maintenance program under there.

In addition, we might note that the recommended level would have exceedances beyond the Kansas City area. In fact, in a research project conducted in a small rural county in the western part of our State with 4,800 residents we did have measurements that would exceed the proposed standard. So, it isn't just a large urban problem.

What we would recommend, and we intend to also formalize these in our comments on the current standard, is that EPA take some more time to review what they propose and, perhaps, consider some of the many things that have been discussed here today that I won't, in the interest of time, go through again.

The depth of the impacts of both the .08 parts per million standard and the PM_{2.5} do bear further examination. And with that I'll be happy to answer any questions.

Senator INHOFE. Thank you, Dr. Hammerschmidt.

Let me ask if Becky Keogh would come up. Becky, can you come up here?

And, Becky, if you could maybe pull that chair up behind Dr. Hammerschmidt in case there are some questions that would be directed to you. We won't recognize you for opening statements, I know you're not prepared for that, but we may ask some questions.

Becky is the deputy director of the Arkansas Department of Pollution Control and Ecology. We're glad to have you here today Becky.

Mr. McBee.

**STATEMENT OF BARRY R. McBEE, CHAIRMAN, TEXAS
NATURAL RESOURCE CONSERVATION COMMISSION**

Mr. McBEE. Thank you, Mr. Chairman, Senators, for the invitation to come and speak to you today about this important issue for Oklahoma, for Texas, for all of our States and particularly to come and speak as one who will be tasked, as you have noticed, EPA with the implementation of whatever standards are finally given to us.

I have provided written testimony for the record, this will be a brief version of that. Let me also note, out of an abundance of caution for the record, that these are my personal views as the chairman of my agency. We have a three-person body that governs my agency and we have no official agency position as of yet. We will develop that and vote on that later on this week.

As has been said many times here today, I know everyone in this room supports clean air. The good news in the State of Texas is that ozone levels are in fact dropping, showing that our standards and our controls are having an impact.

So it was that we in Texas waited, like my colleagues here, along with the other States, for these new EPA standards to be announced, hopeful that they would be a clear mandate that would be fully supported by the scientific community. That is not what has happened.

These proposals from EPA have not established a bright line for the standards. In my opinion, there have to be bright lines for standards such as these. I, as an environmental policymaker in a State with 18 million people and with literally billions of dollars at stake, without a bright line we will be forced to make decisions in the midst of a gray area of science, an area that, as we've touched on today, everyone agrees, seemingly, that not much is certain and there's a great deal that we do not know. We don't have bright lines with these standards. At best we have dim lines.

Now, so it's not as surprising as the finding of Truman Bliley, noted by Chairman Inhofe, we too were surprised recently by a re-

cent action of EPA. Some of you or your staff may be familiar with this.

There was a recent study that has been sponsored by EPA, a study that we in Texas were not notified about until it had been posted on the internet, that has in our minds created even more uncertainties about replacing the 1 hour ozone standard with the proposed 8 hour standard.

This study seems to suggest that the 1 hour standard would be more protective for children in at least two areas of our Nation, in Los Angeles and the city of Houston.

And as I have noted, that has contributed to this atmosphere of uncertainty about the entire process. It appears that truly we do not know as much as we even thought we knew about ozone and we, in fact, do need to know more.

So, because of this we believe the EPA proposals on ozone and particulate matter should be separated, they should be decoupled.

In light of this new study alone we believe it is not good public policy to act now to change the ozone standard. EPA was compelled to move forward on a change to the particulate standard. Now, that is not the case, as you well know, for ozone. If more research is needed on ozone, as it appears there may be, we should do that now instead of prematurely altering the standard which, once again, is working in the State of Texas.

This EPA study also points to another problem. If research shows that different areas of the State of Texas should have different standards to protect their citizens then how is it that EPA can still maintain that one-size-fits-all for the entire country.

This study I've noted has pointed out that what may be good for Dallas/Fort Worth may not be good for the city of Houston. We believe in the State of Texas we should not be called upon then to adopt a separate State standard in addition to a Federal standard that will not fix the problem that EPA has identified.

We believe it is increasingly clear in our Nation that one size does not fit all and that it may be time for a flexible regional approach to clean air and to air quality standard, an approach that is being explored in Texas in certain communities.

Now, we note, if, however, EPA does choose to move forward, and I will echo the concern of Governor Hollister that was out and interventioned by you and your colleagues in Congress, EPA will in fact move forward on this standard.

Let me touch on the proposal itself. EPA proposed an 8-hour standard with .08 parts per million level proposing that some how that is the bright line for the Nation. Let me tell you, in my view that line is in the wrong place.

There is, I think, a growing consensus, if not almost a universal consensus, on the wisdom of an 8-hour standard. You heard the prior panel touch on that. But there is no consensus on the right level for the standard.

EPA chose .08 even though the range of .08, 2.09 or higher was recommended by more of its own clean air science advisory committee and we believe there is no toxicological study which shows more health protection from a level of .09 than one of .08.

Let me also just touch on the particulate matter standard in closing. There we have gone from ozone's dim line to no line at all.

There are very few data on fine particulate matter and based on what EPA is proposing, absolutely no data from monitoring in the State of Texas.

There does appear to be a growing body of evidence that there could be health effects from fine particulate matter. But CASAC, which expressed concern about those health effects, was not even close to a consensus on a standard. It expressed indeed some legitimate concerns and some unanswered questions.

So, what we have to do instead of setting a premature standard is to speed up dramatically the Federal research efforts, which CASAC and the Western Governors Association, joined by my Governor, George W. Bush, called for, and only after that research is concluded decide on a standard, if any.

In closing, it should not be too much to ask, I believe, for government, especially given the potential effects on family, on business and industry, on lifestyle and the staggering cost of these regulations to adopt standards that are both clear and based on sound and compelling science. With so much at stake, the Federal Government is not doing its job if these standards are not clear and if they do not have that basis and, sadly, they do not.

Senator INHOFE. Thank you very much.

Mr. Von Bodungen.

STATEMENT OF GUSTAVE A. VON BODUNGEN, ON BEHALF OF DALE GIVENS, SECRETARY, LOUISIANA DEPARTMENT OF ENVIRONMENTAL QUALITY

Mr. VON BODUNGEN. Thank you. I'm representing Dale Givens, the Secretary of the Louisiana Department of Environmental Quality today, and I also would like to thank the committee for the opportunity to comment on these proposed regulations.

Louisiana, in partnership with EPA has been very successful in improving air quality through the implementation of the Clean Air Act.

Today Louisiana meets five of the six National Ambient Air Quality Standards for criteria pollutants with only ozone remaining.

Our ozone non-attainment parishes have decreased from 20 to 5. We have met our obligations under the 1990 amendments of the Clean Air Act, completing all required emission reductions. We have submitted the required ozone attainment demonstration plan.

As required by the Clean Air Act, complete implementation of the attainment plan will be accomplished in 1999. At that time, we expect to be in full compliance with the present ozone standard. Already, as a result of substantial emission reductions in place, air monitoring data show marked decreases in ozone. Louisiana is on a successful course for cleaner air.

Louisiana supports the establishment of NAAQS which are necessary to protect human health and which are based on sound technical and scientific data.

In the setting of the standards, the EPA has stated that it cannot consider economic or technological feasibility of attaining the standard. We have therefore concentrated our review of the proposal based on the underlying health science including the EPA staff paper and the independent scientific advisory reports.

Based on our study of these documents, Louisiana supports the EPA position that an 8-hour standard is more appropriate for a human health-based standard than the present 1 hour standard. Louisiana also agrees that the form of the standard should be concentration based.

The EPA's staff paper recommends .09 PPM as the upper level of an 8-hour standard that would reduce estimated exposures of the at-risk population sufficiently to provide some margin of safety against pulmonary inflammation and increased susceptibility to pulmonary infection.

Louisiana supports a level of the standard set at .09 parts per million as the 3 year average of the annual third highest maximum 8 hour average ozone concentration.

As we appreciate the underlying science for setting the new standard, little or no public health benefit would be gained by setting the standard at .08 parts per million, that the EPA has proposed, rather than .09.

In addition, Louisiana favors the proposal made by a number of CASAC members for an expanded air pollution warning system that could be implemented for sensitive individuals who could then take appropriate exposure avoidance action. CASAC pointed out to the EPA that this idea would be easy to implement since many areas of the country already have an infrastructure in place to designate ozone action days when voluntary emission reduction measures can be taken. Tulsa, OK, everybody's example, has such a program in place.

For a number of years the Baton Rouge area has operated a program to apply administrative controls on industrial emissions to industrial sources during periods when ozone levels are expected to be elevated.

Efforts to develop a community ozone action day program were begun last summer in Baton Rouge. This effort is expected to continue this summer and is supported by the public.

These are our initial comments regarding the primary standard being proposed for ozone. We are continuing to review the entire proposed set of changes which includes the secondary standard for ozone, the changes to the particulate matter standard and the implementation proposal for both pollutants.

Due to the large volume of documentation associated with these proposals, it will take time to properly review them and the support documentation in order to provide additional comments.

Thank you again for the opportunity to comment today.

Senator INHOFE. Thank you very much.

Mr. Grusnick.

**STATEMENT OF RICHARD GRUSNICK, DEPUTY DIRECTOR,
ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT**

Mr. GRUSNICK. Mr. Chairman, like the rest of the panel, I appreciate the opportunity to offer testimony today on the implication of EPA's proposal of the standards have on State and local government.

There are two basic points I'd like to make today. The first is tightening the standards would divert regulatory resources from the areas with the most serious air quality problems.

The second point I'd like to make is given the difficulty and resistance encountered in identifying and implementing measures to meet the current standard, the credibility of all levels of government will ultimately decline if the proposed standards are adopted.

The only current non-attainment area in Alabama is the Birmingham area which includes Jefferson and Shelby counties.

Birmingham was designated a marginal to least severe ozone non-attainment area pursuant to the Clean Air Act amendments of 1990.

A significant amount of the air regulatory resources in Alabama have been focused in this area by developing and enforcing regulations dealing with smaller types of industries that we don't regulate in the remainder of the State and in focusing on improvements in the transportation system.

This makes sense, we're focusing the regulatory efforts and associated increased costs in the area of the State with the worst air quality where the benefits would be greatest. This focusing of resources would decrease if the proposed standards were adopted.

Under the current range of proposed standards, the number of non-attainment counties in Alabama would increase from two to somewhere between eight and all sixty-seven counties, with the most likely scenario including a minimum of 20 counties being designated non-attainment.

It's not realistic to expect that resources available to the regulatory agencies to be expanded to the level necessary to implement these non-attainment programs with the same level of oversight and detail and thoughtfulness that exists with the current programs.

This will mean that resources will be diverted from the areas with the most severe air quality problems to implement the requirements of the newly designated less severely impacted, less densely populated non-attainment areas.

Given the reality of limited resources, I question whether establishing a tighter standard will actually result in the most effective use of the State's regulatory resources to provide the maximum benefits from cleaner air in Alabama.

I also have reservations about the continued credibility of efforts to improve air quality. The days of easy choices have passed. This is evidenced by the 10 years it took Congress to pass—to reauthorize the Clean Air Act with the 1990 amendments and the challenges already faced in implementing its provisions.

No longer are requiring controls on large industry and the manufacture of lower emitting new vehicles adequate to satisfy the air quality mandates of the existing law. Small businesses are now required to reduce their emissions and lifestyle changes are necessary in some areas.

I have seen presentations by representatives of other more challenged States which indicate emission reductions in excess of 70 percent will be required to meet the current standard. Couple this with the fact that transportation sources are generally responsible for half the emissions and the problem is obvious.

Many of the more severely impacted areas have been unable to develop plans to meet the current standard using any politically or socially acceptable strategy.

Investigations into long range transport have also failed to identify a strategy which would allow the current standard to be achieved throughout the eastern United States.

From a practical perspective, I think it is reasonable to question whether raising the target when the current one is already too high to hit in many instances is the logical thing to do.

In addition, many of the measures recently implemented have met with strong opposition. In the more severely impacted areas smaller businesses have been regulated, automobiles have their emissions tested, and certain types of new industrial growth continues to be essentially precluded by the emission offset requirements.

Tightening the air quality standard would significantly expand the number of areas subject to these requirements and may undermine the support for continued air quality improvement. This is especially likely since these requirements will impact more rural areas which have historically or traditionally been viewed as having good air quality.

It should also be noted, and I think this is important, that continued improvement in air quality will occur even absent a revision to the standards since the aggressive requirements of the Clean Air Act amendments of 1990 have not been fully implemented. They contain many far reaching emission reduction provisions and, again, many of them have not been fully implemented.

Perhaps continued evaluation of the disputed health effects studies would be reasonable as we continue to implement the blueprint for improving air quality established by Congress in the 1990 amendments.

In summary, adoption of the proposed standards would most likely result in diverting regulatory resources from the most impacted areas and a loss of government credibility all the while air quality improvements will continue to be realized as a result of the 1990 amendments.

Thank you.

Senator INHOFE. Thank you, Mr. Grusnick. We will have now one round of questions at 7 minutes apiece, which will put us right up to the 3 o'clock news conference that we'll be having in the Oklahoma Room. So, anyone who is interested in attending that would certainly be welcome to do so.

Let me go ahead and start here. Dr. Hammerschmidt, you mentioned that your State legislatures are taking up a resolution; is that correct?

Mr. HAMMERSCHMIDT. Yes, it is.

Senator INHOFE. When will that be?

Mr. HAMMERSCHMIDT. Well, we just had turn around yesterday so I would imagine it's going to be a couple of weeks before they get—

Senator INHOFE. That would be ample time and we would ask that you would send that to us for our record.

Dr. Hammerschmidt, Kansas City, I assume is—I think the portion of Kansas City that is Kansas was actually out of compliance at one time and then came within compliance; is that correct?

Mr. HAMMERSCHMIDT. Well, actually we've never separated the two. It's just always been the metropolitan Kansas City air shed, which is the five counties.

Senator INHOFE. All right, fine. But they were found to be out of compliance and then you do the fine work that you did and the people in Kansas City did and you came within compliance.

If these regulations were to go through, it's my understanding you would now be out of compliance again?

Mr. HAMMERSCHMIDT. That's correct.

Senator INHOFE. What more can you do? You've done a lot so far, but what more could you do if that should happen?

Mr. HAMMERSCHMIDT. What we have been able to do so far has been primarily to work with the industrial sector within the area to reduce their emissions.

We are currently, as I mentioned, we've had a violation and had a plan developed. We are looking at implementing this summer some public education. We're looking at implementing some of the free riding, free mass transportation ridership, those type of things.

The one thing there's not consensus on at this point is the imposition of an inspection and maintenance program for vehicles and that's one that remains reasonably contentious, both politically and within the city.

In a big picture, it appears to us that in order to get into some of these lessor levels that we're going to have to move more away from the industrial sector and move more into things that effect individuals, such as inspection and maintenance program and that type of thing.

Senator INHOFE. Do you have any idea what—have you quantified the cost if that should happen?

Mr. HAMMERSCHMIDT. No, we have not. We've—I guess our hope has been to find a way to improve the air quality without having to go to inspection and maintenance.

Senator INHOFE. Mr. McBee, I want you to know I'm not one of those who have said that our problems in Oklahoma are due to the prevailing south winds.

Mr. MCBEE. Thank you, Senator.

Senator INHOFE. I notice that in your statement and in your oral statement you repeated it, that recently you gave studies, just last month, I think, shows that the 8-hour standard for Houston would be worse for public health than the current 1 hour standard, and that's the first time we've heard that. Could you kind of elaborate a little bit on that?

Mr. MCBEE. This is an update on part of the risk analysis that was done by EPA. It was done, I think, after they had promulgated these standards and it shows, at least at first blush, we are continuing to analyze it, that again in Los Angeles and in Houston that the existing 1-hour standard provides greater protection, particularly for children, than the 8-hour standard would.

It has caused us, as we determined the State's position on these proposals, to step back and replace the data that's part of the uncertainty that we face. In fact, increased uncertainties.

We believe we knew a great deal about ozone, perhaps we do not know as much as we once thought. So, we would assert that it's time for EPA to step aside, delay this proposal and focus on that

study and any other studies that are in the pipeline. This is not a single isolated incident, perhaps, to make sure that we, in fact, do know and that they in fact do know enough to go forward.

Senator INHOFE. Ms. Keogh, you heard the testimony and the comments made by Mayor Hays. Do you find yourself in agreement from your standpoint as deputy director of the Arkansas Department of Pollution Control and Ecology to be in substantial agreement with Mayor Hays?

Ms. KEOGH. Yes. I appreciate the opportunity to participate today even though I didn't have written comments prepared.

Generally I think my comments wouldn't be different and would reflect many of the same statements that the individuals made as well as Mayor Hays.

I attended the meetings where those resolutions that he presented in his comments were passed and participated in those discussions.

The impacts in Arkansas I think have been discussed, you know, in two areas. I agree that as a State agency and as a professional in this field it's very important that the burden of demonstrating the impacts of these regulations not be left to the State agencies, but be brought forward to the public when the proposal is made. I think that's very important from a professional standpoint and, as they mentioned, for our own credibility in terms of implementing other regulatory programs within the State.

Senator INHOFE. Well, let me ask you this question, and maybe you also, Mr. Grusnick. You've stated, all of you have stated, and it has been an incontrovertible fact, that our air is getting cleaner from the efforts that we have made in the past.

The thing that disturbs me, I guess, from the hearing we had where Carol Browner was there, that she is making the American public believe that our air will get dirtier if these regulations do not get enacted. Would any of you want to comment on that?

Mr. GRUSNICK. Well, again, I think Congress did—again, it took 10 years to amend the law last time, and there was some fairly aggressive things. Phase two of the acid rain provisions, for example, have not yet kicked in. That's where the lion's share of the reduction in oxygen oxide and sulphur oxide emissions are going to come. Both of those, oxygen oxide is implicated with ozone and the small particles, as is sulphur oxide with the small particles, so we have that.

We have the fleet turnover in automobiles that will continue absent anything. Generally the improvements in the transportation system. Increased efficiency of vehicles. There's other regulations that EPA will have to adopt to control the hazardous air pollutants. So, there's a built in continued improvement for some period of time that in my judgment removes the sense of urgency to change the standard right now.

Mr. VON BODUNGEN. I'd like to echo that and I think you've made an excellent point. We've been fighting this ozone standard for over 20 years. I've been in this area since 1970, and I've been the head of it since 1976 and this is an extremely stringent existing standard, it's very stringent.

The feeling is, as you listen to the proposal, we're going to take some kind of quantum leap, when we can't even meet the present

standard, although in a lot of cases we are showing a lot of improvement. As Richard said, there's still a lot of things in the pipeline that are coming down.

A significant amount of the country is serious ozone non-attainment and the compliance deadline for those type of States is 1999. So, we're looking for more improvements under the existing standard.

Senator INHOFE. Well, you know, one of the things that bothers me, I guess, I noticed a lot of masks when we came in here today, and of course in Washington they made a big issue out of that and the media loves it, in spite of the fact that we have made dramatic progress in cleaning up the air in America yet the incidents of various respiratory diseases has gone up, which would leave someone to doubt that it was related directly to that. If the air is getting cleaner why are those increasing. Do any of you have any thoughts along those lines?

Mr. MCBEE. Well, I think part of the body of evidence that does tell you that incidents, for example, of asthma is going up, is attributable to things, perhaps, such as indoor air pollution and not outdoor air quality and then some other just living condition factors.

I mean I know in the city of Houston intensive studies have been done in certain areas that are, for example, lower income housing areas and they find a higher incidence there also which may be attributable simply to the conditions in which people live within their homes and not the outside air that, in fact, they are breathing.

Mr. VON BODUNGEN. I think that there is a dramatic under estimation of the impact of indoor air pollution.

I can't remember the last time I was in a building where you could open the windows.

Senator INHOFE. Well, you know, I just think it's a great disservice to a lot of people with respiratory problems to make them believe something that is not scientifically proven. I find this to be very offensive because I certainly feel sorry for these people.

My time is up. You heard me read the resolution that was passed by the State of Arkansas. I'd just like to have you run down to see if you agree with the sentiments expressed in that resolution. Mr. Grusnick.

Mr. GRUSNICK. Yes, I do.

Mr. VON BODUNGEN. Yes.

Mr. MCBEE. Yes, Senator.

Mr. HAMMERSCHMIDT. Yes.

Ms. KEOGH. Yes, I do.

Senator INHOFE. Thank you very much. Senator Thomas.

Senator THOMAS. Mr. McBee, where would you go for good science?

Mr. MCBEE. Well, I think it may be a question of—science—I don't seek to impugn the science that has been done particularly on the particulate side or on the ozone side.

I mean I will note though that there's the vast difference weight. I think EPA was looking at about a thousand studies in terms of ozone and that drove them to the 8-hour standard. Again, there's concurrence that that's probably the right move.

They're looking at less than 200 studies on fine particulates. So, I think it is just simply the weight of the evidence not that we're

going to the wrong place. We simply have not taken enough time. We have not studied the issue sufficiently and so thoroughly as we need to.

We simply need to, as noted by Senator Inhofe, continue to go forward expending some of the funds that's been dedicated for this purpose, EPA has chosen not to, apparently, yet expend.

Senator THOMAS. EPA, according to their reports have been studying these things now for 4 or 5 years. I guess sometimes I wonder—we talk a lot about peer review for science and so on, in many things, not just this one, and I'm sort of anxious to know how we can feel more comfortable with the science of some of these things.

Dr. Hammerschmidt, is the move from 10 in the particles to 2, is that a big step?

Mr. HAMMERSCHMIDT. I think the answer to that is obviously yes, because we are talking about going to a much finer particulate.

We're also, it's been mentioned a couple of times by other panelists, that we don't even have the monitoring stations designed to do that. We also don't even have the methodology approved as to how we're even going to gather much less evaluate it, so it is a big step.

We think that when we do—and I don't like the word good science as much as complete science. If we get the complete science in we think there might be a big difference between the fine—the $PM_{2.5}$ that you see in a bus barn or in the middle of—in an urban area that you see in a rural area where you're largely getting dust and different type of particles from an unpaved road.

So, we think there is a need for more complete science and the direct answer to your question is, yes, it is a big jump from the PM_{10} to the $PM_{2.5}$.

Senator THOMAS. Someone mentioned difficulty in rural areas. Is this because most of that pollution is natural pollution and there isn't much you can do to control it?

Mr. HAMMERSCHMIDT. Well, it's different because I've lived by unpaved roads and I imagine many of the people here have and, you know, you get a lot of dust and it tends to be very fine dust depending on what the roads are made out of.

That is different than a small particle that's the direct result of combustion, you know, diesel fuel versus road dust.

Some of the effects may be the same, some maybe not. Again, that's where we need to get more of a health study to look at that.

Senator THOMAS. EPA, as I recall, backed away from something awhile back on fugitive dust, took the right step, then replaced it with this which is probably more difficult.

How would you go about regional differential in terms of—I mean the results you want—just because you live one place and I live another you shouldn't ought to have to live with any less quality air than I. How do you do regional things?

Mr. MCBEE. Well, I think the first and foremost is to set good standards nationally. There may need to be a minimum baseline nationally. I think that is, again, we find error in what EPA has done in trying to set these minimum baselines. We do not know enough today.

I think within that then allow communities, and I harken to what Mayor Hays said, allow those local elected officials, the local leaders, to within some range really deal with the priorities what they want to address first.

The city of Houston and the State of Texas is really embarking on that effort now to look at ozones, to look at nitrogen oxide, to look at, perhaps, even some of the critical pollutants such as benzene, and try to craft their own more regionalized approach to deal with what they believe are the most pressing problems today, pressing problems that are decided upon by the local community, not by those in Washington sitting at EPA.

I think within some minimum protection for people all across this Nation there are ways to in fact find these sorts of regional approaches and we need to explore that.

Senator THOMAS. Mr. Grusnick, I think your observation was a good one in that as we move up and have moved up and have generally good air everywhere now you can put your resources where they're most needed. This, I suppose, will spread those resources out again over the whole scope of things.

Mr. GRUSNICK. That's exactly right. I guess in Alabama we have the two counties that are non-attainment for ozone now, if the standard was .08, as proposed, we'd go eight counties be non-attainment. One of them would have a population of 14,000 people. If it went to .07, which is the lower end, it would be 67 counties that would have—all 67 counties would be non-attainment.

So, yes, you know, one approach we could take is to sit here and say, look, if you're going to change these standards you need to give us sufficient resources so that we can do the quality job we've done in other areas throughout—I think that's, given the direction government's going right now, I think that's an unrealistic assessment.

So if you take the other tack and say you're going to have limited resources where can those best be spent. I'd prefer to coax them in the areas that do have the worst air quality and the highest population densities also.

Senator THOMAS. I certainly subscribe to this idea of flexibility and also responsibility for doing it. Thank you Mr. Chairman.

Senator INHOFE. Senator Hutchinson.

Senator HUTCHINSON. Thank you. Let me get this question out of the way. I'll address this to Mr. McBee and then I don't know who it ought to go to, but how are these monitoring sites determined, is it different from State to State? We've got monitoring sites next to airports. How is it determined?

Mr. MCBEE. They are chosen, I believe, with a scientific basis trying to find the worst case possible.

We as a State agency put—

Senator HUTCHINSON. These are consciously put by airports.

Mr. MCBEE. I believe they are. I think there is some credence to doing that. But we seek to—we seek, as a State agency, what we think will really produce the result, if you will, in concurrence with the EPA, we work with them in terms of the siting of these particular monitors.

I think on the belief that if we are identifying the areas of greatest concern, and obviously the air elsewhere within the community is going to be better than that.

Given our existing system, this is one of the flaws in the existing system, where we are looking at a single monitor for a single hour, and that's the right approach, but if we move toward averaging not only over a temporal average over an 8-hour period but perhaps spacial averaging, averaging all the monitors within an area, something that we as a commission support, that will give us a true better picture of air quality. We site monitors today based on the existing system, which I think is a flawed system.

Senator HUTCHINSON. Ms. Keogh, in Arkansas, same thing?

Ms. KEOGH. As I understand it from our staff, I wasn't there when they were located, we worked within specific guidelines or criteria that EPA established in selecting the location.

I agree with Mr. McBee that those standards may not be applicable under the proposed averaging.

We also, I guess the locations—once—this is representative of many things, working with EPA is, that kind of once the State obligates or agrees within those guidelines to place something or, in fact, like in North Little Rock, have two monitors, then what we find is that it's difficult to remove one of those monitors or to move it to a different location within the EPA system.

I believe Mark Coleman mentioned to me briefly that he was successful in moving one by having a garbage truck back up and hit it. That was obviously an accident and not intentional. But, you know, I hope we don't have to go to that extent if we find there is justification to move a monitor.

Senator HUTCHINSON. Dr. Hammerschmidt, walk me through, if these standards on PM should be adopted, what process would you go through to get an area out of attainment into attainment and what kind of resources are we talking about, what kind of time-frame are we talking about, what happens?

Mr. HAMMERSCHMIDT. OK. Senator, the first thing we'd have to do is the monumental task of going around and finding all the areas that were non-attainment.

In other words, with the new methodology and the new sampling procedure, if you will, we'd have to go around to those areas that we felt were most likely to go into non-attainment and that's about—

Senator HUTCHINSON. You don't have monitoring equipment to do that currently?

Mr. HAMMERSCHMIDT. We have no monitors within the State of Kansas that would monitor for PM_{2.5}. I doubt if there's very many States that do.

We have quite a network of PM₁₀ monitors but that data is not useful unless you do an extrapolation.

Senator HUTCHINSON. Do you have any idea how long it would take to do that?

Mr. HAMMERSCHMIDT. Oh, golly, it's going to take a couple of years to get through that whole process just to—you've got to get through the four season changes, et cetera, et cetera.

We would fight the battle with monitor locations, you know, do you put a monitor on the edge of one of the smaller towns, do you put it in the middle of a busy intersection, where do you put a particulate monitor.

Senator HUTCHINSON. Next to the airport.

Mr. HAMMERSCHMIDT. Well, actually where you don't want to put it is probably next to the quarry. But—or next to any kind of road because lots of people don't realize how much dirt there is on a road.

Senator HUTCHINSON. We've used a couple of years, then what happens?

Mr. HAMMERSCHMIDT. What we would then have to do if it was an urban area, like a Kansas City area where we think a lot of the PM_{2.5} is going to be due to dust coming off of paved streets. There's a lot of dirt on a paved street, believe it or not.

Then you're going to have to start looking at this issue of what do you do to control that dust. Do you do wet applications? Do you keep the roads wet—how do you keep that dust down?

In another application, say a smaller town where you might have unpaved roads, you've got the option, obviously, of paving some of them, which is not cheap.

Then you get into the issue that was cited earlier, what if you have an agricultural area located immediately next to an area that's non-attainment and you get a nice midwest breeze, you know, 40 or 50 mile an hour breeze when they happen to be doing the tilling in the spring prior to planting and you're going to get a lot of dust then.

Senator HUTCHINSON. Excuse me, Dr. Hammerschmidt, what you're talking about are various steps you would take then to—

Mr. HAMMERSCHMIDT. Right.

Senator HUTCHINSON [continuing]. To mitigate the containment?

Mr. HAMMERSCHMIDT. Right.

Senator HUTCHINSON. Does everybody agree on the process, is this the steps you'd—

Mr. MCBEE. Senator, I might add, we have looked at the cost in Texas, that's going to be a \$1.5 million to \$2.5 million a year on top of our existing monitoring costs with no offer from EPA to pay those costs.

Mr. HAMMERSCHMIDT. Once you get the monitoring and the mitigation done you would then say—you'd have a plan developed and you'd say this is our plan and we've met it. And that's a—in Kansas City it took us from the mid-1970's clear up to 1992 to get just the ozone attainment taken care of.

Senator HUTCHINSON. What does EPA do during this multi-year, 5 years or so process that you're going through, are you out of—can they at that point start enforcing ISTEA funds or whatever enforcement mechanisms they might want to use?

Mr. MCBEE. There's a possibility of that. There's been discussions, I think, in terms of the implementation policy of these standards to allow time.

Although, we are troubled by some comments we're beginning to hear from EPA that they may move, even with the scarcity of data today about PM_{2.5}, to begin to declare areas as attainment or non-attainment. And that tells you—a very disturbing thought that—very little we know, as you've heard extensively here today, they would begin to make those decisions and potentially move to enforce some of the penalties under the Clean Air Act.

Mr. HAMMERSCHMIDT. One thing we're particularly concerned about is that they have decoupled the setting of the standards from

the—from any discussion of these implementation policies and procedures that they might use. They will not discuss it.

Senator HUTCHINSON. So, we're really in the dark on exactly what process might be—or what they may require or what enforcement may take place if you're out of compliance. Does anybody else want to comment on that before I move on to my next—OK.

Mr. McBee, you mentioned lifestyle and whether it would impact it. We've heard a lot about concerning the barbecuing and so forth. EPA says, and I think correctly, that this standard would not ban barbecues, camp fires, lawn mowing, and so forth.

But if an area was very close, or was very badly out of attainment, could that not be the end result from what the State or local municipalities would have to do to enforce some of those kinds of lifestyle changes?

Mr. MCBEE. Senator, eventually I think it could be. I'm not here to tell you that barbecues will be banned in Texas under these standards or I won't be able to go home.

Senator HUTCHINSON. There would be a wholesale revolt; wouldn't there?

Mr. MCBEE. There would be.

Senator SESSIONS. You don't have any barbecue in Texas; do you?

Mr. MCBEE. If you do look at areas of the country, limitations such as that in terms of use of fireplaces, in terms of use of barbecues, consumer equipment, I mean those things have been talked about and in fact put into place. So, it's not out of the realm of possibility.

Senator HUTCHINSON. I have to quit; don't I?

Senator INHOFE. No, don't quit.

Senator HUTCHINSON. Just one more thing, very simple here. If EPA tells us that their proposed standards could have nothing to do with cost-benefit analysis, but their mandate says health only is what they're to be looking at, and they say, therefore, we're going to go from 10 to 2.5 on PM out of health—for health reasons. Why not even more rigid standards? I mean if going from 10 to 2.5 means better health, and that's their only mandate, and they're not going to consider the cost to industry, the cost to the taxpayers, the costs to local government, or any other factors, then why not make it even more rigid.

Can anybody explain to me how—why 2.5?

Mr. MCBEE. I don't think they can. And I think that is part of the fallacy of their argument that they are simply setting standards, cost is not a factor. That would be true if there were a bright line. There is no bright line and so they have, therefore, entered into a policymaking determination and within that determination cost must be taken into account, I believe, both as a matter of law and certainly as a matter of good public policy.

Senator HUTCHINSON. So, it's arbitrary but there is costs, they really are considering what that cost is going to be they go—I mean—it's unreasonable.

Mr. VON BODUNGEN. I think if they would have ignored that they would have said .07 instead of .08. That will give you an example, they didn't do it themselves.

Ms. KEOGH. Yes, I believe they had data submitted to them that even finer particulate matter would create additional health, you

know, impact. So, you know, I agree with you, there obviously is some policymaking going on.

What the basis of that is is not clear to other State agencies and that's what, you know, really concerns me as being the implementing agency for these standards obviously, as we have today, to some extent we'll take the heat on that and I think we, again, have to be able to provide, you know, credible justification.

Senator HUTCHINSON. Thank you, Mr. Chairman.

Senator INHOFE. Thank you, Senator Hutchinson.

Senator SESSIONS.

Those fine and ultra fine particles, someone has even suggested it may be the ones that are really causing the health consequences may be smaller than 2.5. Do you think that's possible?

I mean we don't have the science right now to show whether it's a 2.4 or 2.5 or 1.0 that may be the triggering particle that cause the health consequences, whatever that is.

Mr. Grusnick, we've been talking about improving the air, I know you've been involved in the State of Alabama in air quality since 1972.

Mr. GRUSNICK. Yes.

Senator SESSIONS. You've seen the whole history of it, I suppose?

Mr. GRUSNICK. I like to tell people I've had 26 years of experience and they said, no, you've had 1 year experience 26 times. So, I hope they're wrong.

Senator SESSIONS. Just one question. Tell us about Birmingham. What have you observed that they've accomplished since—in those 26 years?

Mr. GRUSNICK. Well, while I grew up in Birmingham in the pre-1970's and it had about, on some rankings, the third worst air quality in the country primarily due to particulate emissions from industrial sources. That's back when being an air pollution regulatory was fun, going to the big industries, say make them cleanup my air and, you know, you really got a lot of support for that.

By regulating about 55 companies back then we made dramatic air quality improvements. We measure levels three times the Federal standard. We've not measured a violation of the particulate standard in the past 10 years.

So, there was a lot less ambiguity about how much should you spend to get what level of improvement. Most of these folks didn't have controls back then.

You know, every time we've had a debate about clean air over the years there's been this issue it's going to cost so much, it's going to be impossible to make—take this step and this sort of thing. As it turned out a lot of the predictions about it being impossible to do turned out not to be correct.

But I think we are really getting to the point now where there's more credibility, where maybe it's just—maybe there really is a wolf out there that people are hollering about.

You know, again, you've done most of the subject in with the very large industries. We're getting down to the smaller business people now.

I'll give you some idea. In Birmingham we've had to go through a couple of iterations in adopting new regulations for sources there

to reduce hydrocarbon emissions to hopefully meet the ozone standard.

In 1979 we adopted some regs that got us 6,000 tons per year reduction by regulating 14 sources. That resulted in 450 tons per year emission reduction for each we regulated.

In 1985 we got a 12—some more regulations, 1,200 tons per year reduction in emission—excuse me, 10,000 tons per year reduction with 1,200 sources regulated, eight tons per new source regulated.

So, the more people you impact with new regulations I think the more people pay the cost as opposed to get the benefits.

I think that's one of the things that's causing some of the resentment for government regulation now is that we're getting into the bowels of society, if you will.

Senator SESSIONS. Dr. Hammerschmidt, on—one of the things that was said, I believe in the hearings when Ms. Browner was there, was that .09 would be equivalent to the present .12 standard since it was on an 8-hour basis rather than the 1 hour basis.

I believe you and others suggested you don't agree with that, that .09 would in fact be a higher standard than the present standard?

Mr. HAMMERSCHMIDT. I believe so.

Senator SESSIONS. Of course, .08 would be an even higher standard. So, it's a significant move on ozone also. Any disagreement with that?

One of the things that was commented, we talk about budgetary concerns, and perhaps we do need to spend on the science, but one of the comments by one of the scientists who served on the EPA board was, and he was very critical of them, they had only spent 10 percent of their budget on dealing with these kind of studies when we knew we was facing this 5 year cycle.

Do any of you have any comment on whether—on that comment, any thoughts or observations?

Mr. MCBEE. Well, I think one of the roles that EPA today plays, and must continue to play, is to be, I think, the scientific body for us. We don't have those resources at the State level usually to engage in these sorts of studies.

So, when they are instructed and they're given the opportunity to spend these dollars I believe they really have the obligation and the responsibility to spend them and spend them wisely.

They don't do any of us, as State regulators or the people of this country, a service by not expending the funds that are given to them for that purpose.

Senator SESSIONS. Mr. Chairman, on the comments, I think some have mentioned today that EPA is under a Court ordered deadline. They asked for some additional time, the Judge only gave them 21 days.

But I think it's important to note that the deadline is not to impose these standards. The deadline is merely to evaluate and set new standards if they need to be set.

So, the Court—I've seen this over and over and over again, that our governmental agencies say they've got to do something that's unpopular because they've been made to do so by the Courts and that is not the case in this circumstance.

Mr. VON BODUNGEN. I'd like to comment a little bit there. I agree with Mr. McBee that these two should be separated because one of them is being driven by a Court—one time line driven by a Court suit but the other one isn't.

Frankly, it's a very tough cycle. Five years is just too tight to do good science and to really get into the study. You can't rush to judgment on these type of things. You want to make sure you do the right thing.

Mr. MCBEE. If you break apart these numbers in terms of the cost of the ozone versus the particulate standard and the benefits, those numbers are dramatically different, particularly the ozone standard, that there may not be an appreciable benefit in terms of financial—a financial benefit to the country in terms of cost to the industry for regulation versus avoiding costs in terms of health care costs. There may actually be a real cost as we read the numbers to the ozone standards.

Ms. KEOGH. I guess from our perspective in Arkansas what I would prefer to see, I guess, when EPA reviews things like this that they come back with recommendations, they don't necessarily have to adjust the standards.

I think we would all agree that there may be health data that indicates a possible problem and that perhaps the common sense and scientific thing to do is to go establish real life monitoring data. That may be the more appropriate recommendation as opposed to actually starting to adjust numerical standards.

Senator SESSIONS. Mr. Chairman, I'm not sure I have it straight, being new to this area, but it seems to me is it 60 days—they have 60 days notice to the world that these standards are going to be imposed. It seems to me that is—is that—

Senator INHOFE. Well, first of all, the 60-day comment period was extended by 21 days. However, if you recall, we passed in the last session of the legislature the Flexibility Act, which gives Congress veto power over the regulators. So, that we as—in our committee, the committee that we all sit on, decide that we disagree with these we can go ahead, have our meeting, take it to the House and the Senate all in the same day but then of course we'd be subject to, perhaps, a Presidential veto, in which case then you have to come up with two-thirds.

So, as it is right now, the timing goes into June before we would have the opportunity to invoke the provisions of the Bill. Incidentally, Don Nickles, who was the author of that Bill that passed in 1994. So, that's kind of the time line.

Senator SESSIONS. Well, my only thought was 6 months or so might be good to—if you really wanted your comments and the comments from the science, the EPA, environmental management agencies in the States, 6 months or even more may be an appropriate time as a matter of policy.

If you were writing the law would you ask for that much time or more? Anybody disagree with that?

I just think that would be a natural way to do it unless we were in an emergency situation.

I guess that's all. Thank you, Mr. Chairman.

Senator INHOFE. Any further comments?

Well, first of all let me thank the witnesses for appearing today.

We will be having a news conference in just a few minutes in the Oklahoma Room, it's scheduled for 3 o'clock, we'd invite the witnesses, any witnesses from any panel who are still here to join us.

This hearing is going to be recessed, not adjourned, we're going to hold it open for 3 weeks so that we can get documents, such as we discussed, Dr. Hammerschmidt, that can be entered as part of the record.

Today we heard from officials from seven States, included the national representatives from the U.S. Conference of Mayors, League of Cities, National Conference of State Legislatures.

Briefly, I put down six, what I consider to be results that everyone agreed to. No. 1, that the cost is far greater than the EPA estimate. In fact, the \$3.5 billion for Ohio alone would certainly verify that.

Agreement that the EPA violated unfunded mandates. Non-attainment status affects competition, jobs and makes it hard to attract business. Implementation steps would affect small businesses. Create lifestyle changes.

No. 5, the States have no monitoring systems, in fact, don't know how to implement one for particulate matter.

And, last, States and cities are not convinced that the science is sound. In fact, they believe more research is needed, which is exactly what the panel said, the scientific panel that is statutorily obligated to advise the EPA.

So, again, I appreciate very much your coming. And more than anything the 35 people that endured 4 hours. Now you know what life is like in Washington.

Particularly my colleagues, Senator Thomas, who had to catch a flight, Senator Hutchinson and Senator Sessions for coming and using up this day of no votes to help us out here in Oklahoma determine how real people think.

We are recessed.

[Whereupon, the subcommittee was adjourned, to reconvene at the call of the chair.]

[Additional material submitted for the record follows:]

Commission's Primary Recommendation on EPA's Proposed Revisions to the Particulate Matter Standard

The Texas Natural Resource Conservation Commission (commission) agrees with the Clean Air Scientific Advisory Committee's (CASAC) assessment that there is information indicating potential public health impacts from fine particulate matter (PM_{2.5}). However, there was no consensus among CASAC panel members as to the appropriate level. The divergent opinions expressed by CASAC members are reflective of many unanswered questions and large uncertainties. Such concerns include but are not limited to: 1) the influence of confounding variables, 2) measurement errors, 3) the existence of possible alternative explanations, 4) the lack of understanding of toxicological mechanisms, 5) exposure misclassifications, and 6) the use of different models in the health studies. Based on the widely divergent views of the CASAC members, the lack of a sufficient data base to characterize or understand PM_{2.5} levels, and the concerns listed above, the commission believes that it would not be prudent public policy to go forward with the setting of a new PM_{2.5} standard at this time. The commission also supports the Western Governors Association's Resolution 96-025 urging the EPA to implement the targeted research program called for by the CASAC to reduce the uncertainty associated with our current understanding of fine particulate matter before establishing a new PM_{2.5} standard or revising the PM₁₀ standard.

Secondary Recommendations

Should the U. S. Environmental Protection Agency (EPA) choose to go forward with establishing a new PM_{2.5} standard, the following is a detailed explanation of the commission's position on the proposal.

Averaging Time

Short-Term PM_{2.5} (24-hour) Standard: Based on the majority opinion of the CASAC members the commission believes that if a PM_{2.5} standard is found to be necessary at this time it would be appropriate to establish a 24-hour standard.

Long-Term PM_{2.5} (Annual) Standard: If the EPA goes forward with establishing a PM_{2.5} standard, the commission would support the majority CASAC recommendation for the use of an annual standard. The commission believes that an annual average measure is more stable over time than a 24-hour standard because the 24-hour standard can be greatly influenced by short term meteorological variations.

Form

Annual Standard: The commission believes that a concentration based annual standard would reduce the broad distribution of PM_{2.5} concentrations. The commission supports the concept of spatial averaging because it believes that spatial averaging can provide a better indicator of the population exposure actually experienced within the averaged area. This is important because many of the community-based health studies relied upon by EPA used spatial averages to

characterize the area-wide PM exposure levels. Additionally, a spatially averaged form provides additional statistical stability and accuracy of monitored values. The commission supports investigation and analysis of results from individual monitors that may experience slightly elevated annual concentrations above the spatially averaged standard.

24-Hour Standard: The commission would support the use of a concentration-based 98th percentile averaging form for the 24-hour standard. Exposure to $PM_{2.5}$ is dependent on the actual magnitude of the concentration, not just whether the concentration is above a specified level. In addition, a concentration-based percentile form is a more statistically stable and robust form compared with an expected-exceedance form. The use of a concentration-based form of the standard would improve the year-to-year stability of an area's attainment status and reduce the impacts of single high events that may be due to unusual meteorological conditions.

Levels

The majority opinion of CASAC indicated that a new $PM_{2.5}$ standard should be established. However, there was no consensus among CASAC panel members on the appropriate level. As stated in CASAC's closure letter, the panel members' opinions were divided into three broad categories: 1) four panel members supported levels toward the lower end of EPA's staff recommendations; 2) seven members supported levels near or above the upper end; and 3) eight panel members declined to select a level. The divergent opinions expressed by CASAC members are reflective of many unanswered questions and large uncertainties. Such concerns include but are not limited to: 1) the influence of confounding variables, 2) measurement errors, 3) the existence of possible alternative explanation, 4) the lack of understanding of toxicological mechanisms, 5) exposure misclassification, and 6) the use of different models in the health studies. Because of the widely divergent views of the CASAC members, the lack of a sufficient data base to characterize or understand $PM_{2.5}$ levels, and the concerns listed above, the commission believes that if necessary to establish $PM_{2.5}$ standards at this time, it would not be prudent public policy to set levels any lower than 20 micrograms per cubic meter for the annual standard and 65 micrograms per cubic meter for the 24-hour standard.

Retention of the PM_{10} Standards

Annual Standard: The commission would support the CASAC's recommendation "that retaining an annual PM_{10} NAAQS at the current level is reasonable at this time".

24-Hour Standard: The EPA states in the proposal "it is possible that the current annual standard [PM_{10}] might provide adequate protection against both long and short-term effects of coarse particles, especially when viewed in conjunction with the overall proposal to add new annual and 24-hour $PM_{2.5}$ standards". The EPA also states in the proposal that the analysis of available air quality relationships between annual and 24-hour PM_{10} levels show that such a standard might not add greatly to the protection provided by the current annual standard. Additionally, nearly half of the CASAC panel members recommended that the 24-hour PM_{10} standard be revoked. Therefore, the commission recommends against retaining the 24-hour PM_{10} standard and believes it would be an imprudent use of resources. However, should the EPA choose to retain a 24-hour

PM₁₀ standard the commission agrees with the CASAC recommendation of using a concentration-based 98th percentile form of the standard.

Conclusion on the Secondary Standard

If a PM_{2.5} standard is necessary at this time, the commission supports the setting of a secondary PM_{2.5} standard identical to the primary standard and that both should be set no lower than 20 micrograms per cubic meter (annual) and 65 micrograms per cubic meter (24-hour).

Area Designations

The commission also believes that it would be inappropriate to base attainment designations on anything less than actual monitored data. Based on the lack of monitoring data and the many uncertainties associated with PM_{2.5}, the commission believes it would be inappropriate to designate areas using a ratio method or any other method not based on actual monitored data.

Draft

The Texas Natural Resource Conservation Commission (commission) has carefully reviewed all available information about the U.S. Environmental Protection Agency's (EPA's) proposal to change the ozone standard and has concluded that there truly is no "bright line" in the standard setting process. EPA's science advisory panel, the Clean Air Scientific Advisory Committee (CASAC), stated that there is no bright line that distinguishes a level for an eight-hour standard between 0.07 parts per million (ppm) and 0.09 ppm, and a form of between 1 and 5 expected exceedances. Now, EPA's own recent supplemental ozone exposure and health risk analyses also show that there is no bright line in setting an averaging time, and indeed call into question the assumption that one particular averaging time, form, or level is appropriate for all areas in the nation.

Commission Primary Recommendation

The commission believes that EPA should retain the current one-hour primary and secondary ozone standards at this time.

On February 11, 1997, Harvey Richmond, of EPA's Risk and Exposure Assessment Group issued a memorandum entitled **Supplemental Ozone Exposure and Health Risk Analyses**. This memo summarized recent findings of two EPA contracted documents. One is titled **A Probabilistic Assessment of Health Risks Associated with Short-Term Exposure to Tropospheric Ozone: A Supplement** by R.G. Whitfield of Argonne National Laboratory. The other is **Supplement to 'Estimation of Ozone Exposures Experienced by Outdoor Children in Nine Urban Areas Using a Probabilistic Version of NEM (April 1996)'** by Ted Johnson of TRJ Environmental Inc., et al. Both of these document updates were published in January, 1997. These documents were updated at EPA's request after the proposed revision to the primary ozone standard was published. These updates contain several refinements to modeling assumptions, including an analysis of the risk exposure associated with EPA's proposed level and form, and different rounding conventions, which were lacking in the original risk exposure analysis.

A review of these documents shows that for seven out of nine selected cities, the risks of both exposure to levels above the standard and "large" lung function decrements to outdoor children associated with EPA's proposal are less than that under the current standard. However, there are two notable exceptions to this trend. The risk exposure analysis for both Houston and Los Angeles projects that fewer outdoor children would be exposed to and suffer the effects of elevated ozone levels under the current one-hour standard than under EPA's proposal for an eight-hour standard.

At the very least, the commission believes that this study, which shows different public health outcomes for cities attaining an eight-hour standard, reveals that the science is not sufficiently conclusive to make a decision on the appropriate averaging time for the primary standard. The commission is extremely concerned about these findings and in light of them recommends that the

current one-hour standard be retained at this time, and that further study be initiated to determine the advisability of moving to an eight-hour standard for the entire nation. For example, Houston and Los Angeles have design values for the one-hour standard that are 50 parts per billion (ppb) or more higher than those of the next highest city, New York. They are also both warm, southern coastal cities, unlike the other study cities (except for Miami, which had an extremely low one-hour design value in the study). Other southern cities like Atlanta and Dallas were not studied, and cities currently in attainment that would be nonattainment under the proposed standard, like San Antonio, were also not studied. Therefore, it is not known whether the results for Houston and Los Angeles differ from those of the other cities because of their high ozone values or because of their geographic similarities. In order for the commission to support an eight-hour standard, a fuller understanding of why Houston and Los Angeles experienced different outcomes than the other study cities would be necessary, as would an analysis of other major Texas cities and cities around the nation with similar geographic features.

The commission believes that these studies are absolutely essential to making a public health-based decision on the best science available. These studies cannot be completed in the time frame mandated by the courts for the particulate matter standard decision. Therefore, the commission recommends that EPA decouple the timelines for promulgation of the ozone and particulate matter proposals and delay promulgation of the ozone standard until further necessary studies have been performed.

The commission believes that cities such as Los Angeles and Houston may well be unique in their air pollution problems due to their source mix and prevailing meteorological conditions. If further study proves that they are, the commission believes that a "one-size-fits-all" approach to standard setting may not be prudent on a national basis, and that regions may have to choose an averaging time for an ozone standard that provides the greatest protection to the public. Of course, this choice would have to be based on sound science, and under no circumstances should areas be forced to comply with two national standards.

The commission believes that significant progress in understanding key scientific and public policy aspects of air pollution control has been made by the Federal Advisory Committee Act's (FACA) Subcommittee on Ozone, Particulate Matter, and Regional Haze. The commission recommends that regardless of the ozone standard averaging time eventually promulgated by EPA, this vital work should continue and its results should be incorporated in the state implementation plan process, as appropriate.

Secondary Recommendation

The commission believes that EPA, based on the uncertainties which arise from their new information should retain a one-hour standard for now. However, the commission recognizes that due to other factors, EPA may choose to promulgate an eight-hour standard, and offers the following comments as a secondary recommendation.

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Level

The commission does not support the 0.08 ppm level proposed by the EPA, nor would it support a lower level. The commission supports a level of at least 0.09 ppm for the following reasons.

Both CASAC in its closure letter on the proposed primary ozone standard dated November 30, 1995 and EPA have determined that ozone may elicit a continuum of biological responses down to background levels. Therefore, it is not possible to select a level below which absolutely no effects are likely to occur. CASAC and EPA have agreed that in the absence of a "bright line" which clearly demonstrates a level at which exposure to ozone begins to cause adverse effects, the selection of a specific level is a policy judgment. The level proposed by EPA may result in five new areas in Texas not meeting the new standard, more than doubling the number of areas that do not meet the current ozone standard.

EPA lacks a scientific basis on which to choose between a 0.08 ppm and 0.09 ppm level for an eight-hour standard, because there are no demonstrably greater health benefits to be gained at any specific point within the range of 0.07 ppm to 0.09 ppm. In the absence of compelling scientific evidence, the selection becomes a policy decision. The commission believes that the following elements of good public policy should form the basis for EPA's decision on the level of the standard.

Attainability. Is the proposed standard reasonably attainable? There are serious questions about the attainability of a proposed standard that approaches background concentrations. In its own Regulatory Impact Analysis (RIA), EPA states that

For some counties the analysis finds that the control measures identified in the cost analysis would not be sufficient to result in attainment of the alternatives by 2007...(t)here are likely to be cases in which currently identifiable controls are not enough to reach attainment of the revised standard by 2007, which is the attainment date for certain nonattainment areas under the current standard.

Houston is one of the areas identified in the RIA for which not enough control measures could be identified for it to reach attainment of the proposed standard. If there are not enough control measures identifiable at any cost that would allow Houston to reach the proposed standard, for all practical purposes it is not attainable.

Reasonableness of costs incurred in light of benefit gained. EPA has argued that costs cannot play a role in the standard setting process based on judicial interpretation of the Federal Clean Air Act. The commission believes that this can be the case if a clear scientific determination of health effects could be demonstrated. However, neither EPA nor CASAC can determine a bright line which distinguishes any of the proposed standards as being significantly more protective of human health. Therefore the setting of the exact level has become a policy decision. Because it is a

policy decision, a cost/benefit comparison of alternatives can and should properly be taken into consideration. Furthermore, costs to the public versus benefits is a vital public health consideration. All other public health and welfare decisions (e.g., building codes, immunization requirements, automobile safety requirements) are based on some determination that a certain level of control is necessary and therefore the costs should be borne by society. Conversely, some other level of control, while perhaps technically feasible, is too costly, and will therefore not be required.

EPA has stated in their fact sheets that the monetized net health benefits for the proposed new standards (ozone and PM fine combined) are estimated to be between \$76 billion to \$134 billion dollars. However, a closer reading of EPA's back-up documentation (including the Regulatory Impact Analysis), reveals that most of the monetized benefits are realized from attaining a PM fine standard, and that there is actually a small net monetary loss of up to \$2 billion dollars incurred by attaining the proposed ozone standard. The commission believes that a full cost-benefit analysis should be performed and that the costs and benefits of the continued implementation of the Clean Air Act Amendments of 1990, the Ozone Transport Assessment Group (OTAG) recommendations, and the costs and benefits of the Interim Implementation Policy should be factored into the analysis. The commission believes that including these programs in the analysis will more accurately assess the true cost of all programs which will contribute to attainment of the proposed new standard.

Flexibility of decision-making in light of uncertain science. Before additional regulations and costs are placed on the public, the federal and state governments have an obligation to be sure that those costs are required for the protection of public health. If the standard is set at 0.08 ppm, many areas that currently do not violate the one-hour standard will not comply with the eight-hour standard. They will be required to begin expensive control programs. If later scientific evidence definitively shows a level of 0.09 ppm to be protective of health, these areas will have sustained a considerable economic loss for little or no benefit. However, if the level is set at 0.09 ppm, the areas with demonstrated air pollution problems will be required to implement control strategies. If a level of 0.08 ppm is later scientifically demonstrated to be necessary for the protection of health, the reductions made by the areas that could not meet the 0.09 ppm standard will have helped them attain or make progress toward attainment of a 0.08 ppm level.

The commission believes that when all of these factors are taken into proper consideration, a level of at least 0.09 ppm would be the correct public health and public policy choice at this time for an eight-hour standard.

Form

The commission supports a form expressed as the three-year average of either the third, fourth, or fifth-highest maximum eight-hour average ozone concentration. The commission believes that such a form more accurately reflects the exposure of the population to ozone levels of concern.

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Also, this form is less subject to random perturbations caused by meteorological variations, like those seen in the years 1988 and 1995.

EPA has stated that for an eight-hour standard at a level of 0.09 ppm, it will only consider a form of the eight-hour average of the annual third-highest maximum eight-hour average ozone concentration. The commission believes this position is not justified by sound science. EPA stated, and CASAC concurred, that the form of the standard, as long as it is within the range of 1-5 expected exceedances (or an equivalent concentration-based form) does not provide a significant difference in the amount of risk exposure for the population at large (although all members of CASAC favored a multiple-exceedance based form of the standard). If EPA cannot identify a bright line which distinguishes between a form within the range of 1-5 expected exceedances, this too becomes a policy judgment. Therefore, the factors described above in the discussion about the level of the standard regarding attainability, cost/benefit impact analysis, and flexibility in light of uncertain science also pertain to the decision making on the selection of the form of an eight-hour standard. The commission believes that EPA should select a form which provides for maximum statistical stability.

Some studies indicate that some extremely sensitive individuals may be affected by shorter-duration levels that exceed the 0.09 ppm level. The commission believes that an expanded public notification system, based on improving techniques to predict elevated ozone levels in advance which EPA discusses in the Pollution Standards Index section of the proposal, will provide an adequate margin of safety to those extremely sensitive individuals considering the few times that such preventative measures would actually be required. The commission also supports investigation and analysis of monitors that frequently experience elevated levels of ozone. Given this additional margin of safety, the commission believes that the combination of this form and level of the standard will provide health protection to the public.

Spatial Averaging

The commission supports the concept of spatial averaging because it believes that spatial averaging can provide a better indicator of the population exposure actually experienced within the averaged area. Additionally, a spatially averaged form provides additional statistical stability and accuracy of monitored values. However, the commission believes that a complete analysis of whether the type of spatial averaging being considered by EPA is adequately protective of human health can only be done after further protocols are established to determine the method of conducting spatial averaging.

Furthermore, the commission shares EPA's concern that spatial averaging can only be done in areas that have an adequate monitoring network, and that developing a siting protocol will be difficult. However, the commission believes that spatial averaging, in conjunction with Urban Airshed and other modeling techniques, could provide an effective mechanism for redeployment of the ozone monitoring network, and provide an incentive to states for this redeployment. The

commission believes that an expanded public notification system, combined with improving techniques to predict elevated ozone levels in advance, could help provide an adequate margin of safety for extremely sensitive individuals. As stated above, the commission also supports investigation and analysis of monitors that frequently experience elevated levels of ozone.

Proposed Decision on the Primary Standard

If an eight-hour standard is promulgated, the commission does not support EPA's proposal to maintain the current one-hour standard until the State Implementation Plan (SIP) for the proposed new eight-hour standard is approved. More often than not, a long period of time passes between when the state has legal authority to implement control programs and when EPA approves a SIP. In many cases, this is of little concern, although it causes confusion in the mind of the public and the regulated community. In the case of the new standards, however, working under an interim policy based on a one-hour standard could impose a significant burden on states and the public, and hamper efforts to move toward attainment of an eight-hour standard.

All states have some mechanism for making control programs enforceable in their state, although each state's mechanism is slightly different. The commission believes that the one-hour standard should cease as soon as states have legal authority to implement and enforce control strategies to move toward attainment of the eight-hour standard and submit a SIP containing those strategies to EPA, rather than waiting for EPA approval of that SIP.

Communication of Public Health Information

The commission supports the continued use of the Pollution Standards Index (PSI), and EPA's suggestion to revise the PSI to include an expanded warning system. The commission believes that this warning system, combined with the level and form described above, provides important public health information to those extremely sensitive members of the public who might be affected by slightly elevated levels of ozone. The commission also supports EPA's plans to increase the ability of forecasters to project an ozone episode a day in advance. The commission provides previous-day forecasting to several nonattainment and near nonattainment areas in Texas for their voluntary episodic ozone control program, and would welcome the opportunity to work with EPA and other states and localities to improve forecasting and public notification efforts.

Conclusions on the Elements of the Secondary Standard

The commission supports setting the revised secondary standard identical to a proposed eight-hour standard of at least 0.09 ppm. The commission believes that controls to achieve an eight-hour standard of 0.09 ppm will reduce vegetation exposure during the growing season, and that without further scientific evidence, the secondary standard should not be more restrictive.

The commission does not support the "SUM06" seasonal exposure index for the secondary standard. The current monitoring network does not measure rural ozone levels, so estimates of counties that would not be attainment under the SUM06 are based on urban monitors and do not reflect the large rural areas between urban areas of Texas. Analysis performed by the state indicates that the form is highly unstable and is very dependant on large-scale meteorological fluctuations. For these reasons, the commission does not support a new secondary standard different from the primary standard.

Data Completeness

The commission supports with modification the proposed revision to Appendix H concerning data completeness. The commission believes that 90% data completeness for a three-year period and 75% for a single year are reasonable levels on which to base compliance with the standard, but only if hours when a monitor is undergoing a quality assurance check (such as a calibration check) are not counted for purposes of completeness. The commission recommends that surrounding hour data and historical trends be used to verify that ozone levels are low during these periods in order for those hours to be presumed complete. The commission further supports EPA's proposal to use meteorological data to provide an objective basis for determining if meteorological conditions were not conducive to high ozone levels for days with missing data. The commission has performed this type of analysis on several areas within Texas for numerous days, and finds this analysis, in conjunction with analysis of surrounding monitored values, to be a strong predictor of ozone levels.

Data Handling and Rounding Conventions

The commission believes that reporting ozone levels to three decimal places will eliminate public confusion about the level at which an exceedance actually occurs. However, EPA's protocols for ozone data monitoring call for calibration with a tolerance of plus or minus 15% (or within approximately 0.013ppm for the current standard of .12ppm). Acceptable modeling performance statistics are even greater. Therefore, it is inappropriate and inconsistent to report data to such a level of precision that is beyond the capability of the current monitoring and modeling tools to capture.



February 28, 1997

U. S. Environmental Protection Agency
 Air Docket # 6102 (A-95-58)
 Waterside Mall, 401 M Street, S.W.
 Washington, D.C. 20460

To whom it may concern:

Metroplan is a council of local governments based in Little Rock, Arkansas and the designated metropolitan planning organization (MPO) for the Little Rock-North Little Rock Metropolitan Statistical Area (MSA). Metroplan has twenty-four (24) members that include: the Arkansas State Highway and Transportation Department (AHTD), four (4) county governments, eighteen (18) municipal governments, and the Central Arkansas Transit Authority (CATA). Our transportation planning process is established through inter-local agreements and referred to as the Central Arkansas Regional Transportation Study (CARTS). On Wednesday, February 26, 1997, the Metroplan Board of Directors (MPO) approved the following comment for the Federal record and directed staff to submit it to the U.S. Environmental Protection Agency.

We support the U. S. Environmental Protection Agency (EPA) proposal for an 8-hour concentration based national ambient air quality standard for ground-level ozone, since "...the 8-hour standard is more directly associated with the health effects of concern cited in recent 6- to 8-hour exposure studies..." and was unanimously recommended by the Clean Air Scientific Advisory Committee (CASAC). We also support EPA's position of using the conventional rounding convention, with respect to determining violations of a revised ozone standard. However, we do not support setting the standard at 0.08 parts per million (ppm) using a form of the third highest daily maximum averaged over three years, since CASAC could not achieve a consensus on either the appropriate level or form for an 8-hour ozone standard. Therefore, we urge EPA to consider promulgating either of the following alternative 8-hour concentration based ozone standards, which we believe would afford improved protection over the current standard for the general public likely to be exposed, as well as persons most at risk:

- average third highest daily maximum, set at 0.09 ppm; or
- average fifth highest daily maximum, set at 0.08 ppm.

Sincerely,

Jim McKenzie
 Executive Director



February 28, 1997

U. S. Environmental Protection Agency
 Air Docket # 6102 (A-95-54)
 Waterside Mall, 401 M Street, S.W.
 Washington, D.C. 20460

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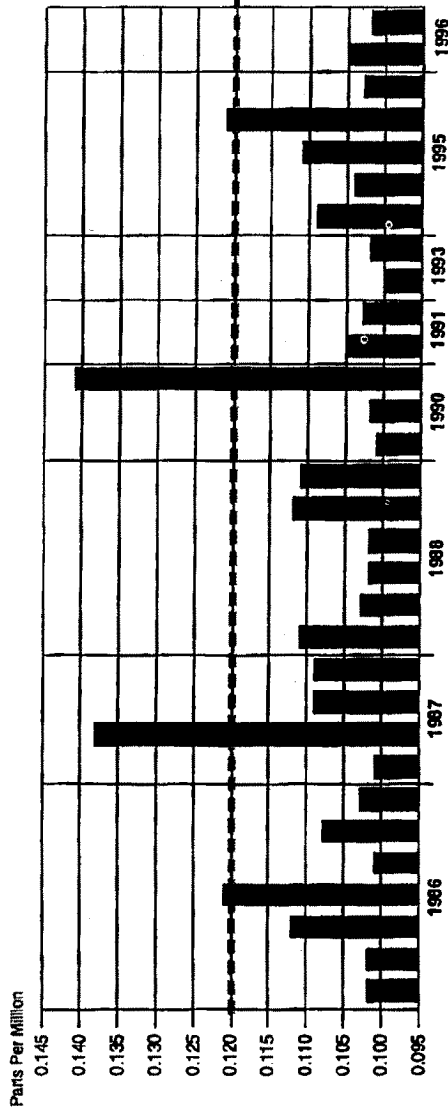
We believe there is a lack of monitoring data available on the extent and sources of fine particulate matter, denoted as $PM_{2.5}$. In addition, because of the connection between the Clean Air Act Amendments of 1990 (CAAA) and the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), the consequences of $PM_{2.5}$ nonattainment could be quite severe. We urge EPA to first establish a monitoring protocol and then require all states to monitor $PM_{2.5}$ for a period of up to 3 years without regulatory consequences. After sufficient monitoring has occurred, the data should be analyzed to determine the contributions from man-made and natural sources. If, for example, natural sources are a major component of $PM_{2.5}$, the approach of controlling man-made sources could prove fruitless. After this data and analysis, the standards should be subject to another public comment period, and the public would then be better informed regarding the consequences.

Sincerely,



Jim McKenzie
 Executive Director

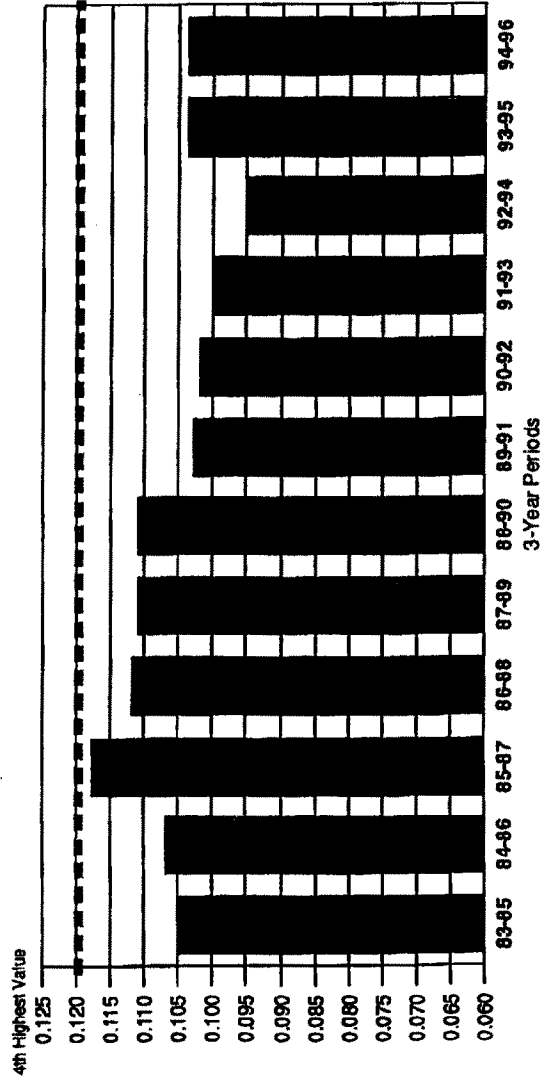
1 Hour Ozone Values > 0.999 PPM 1986 - 1996 At NLR Airport



METROPLAN

Source: ADPC&E

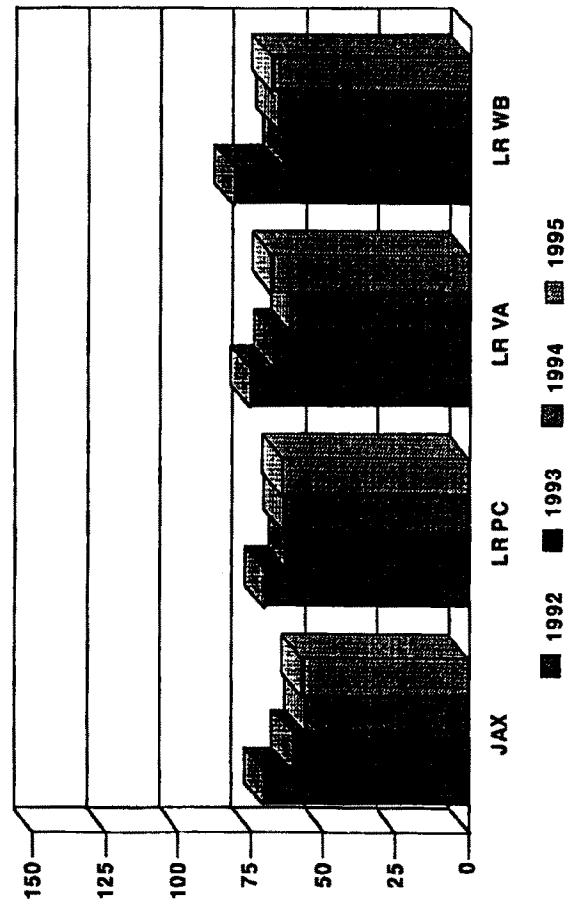
4th Highest 1-Hour Daily Maximum In Three Years 1983 - 1996 At NLR Airport



Source: ADPC&E

METROPLAN

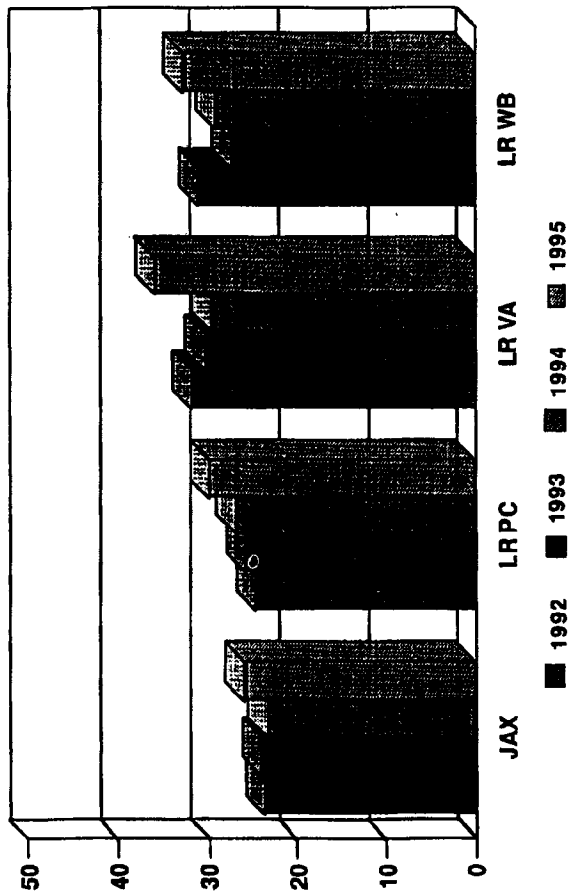
Highest 24-Hour PM-10 Averages 1992 - 1995



Source: Arkansas Department
Pollution Control & Ecology

METROPLAN

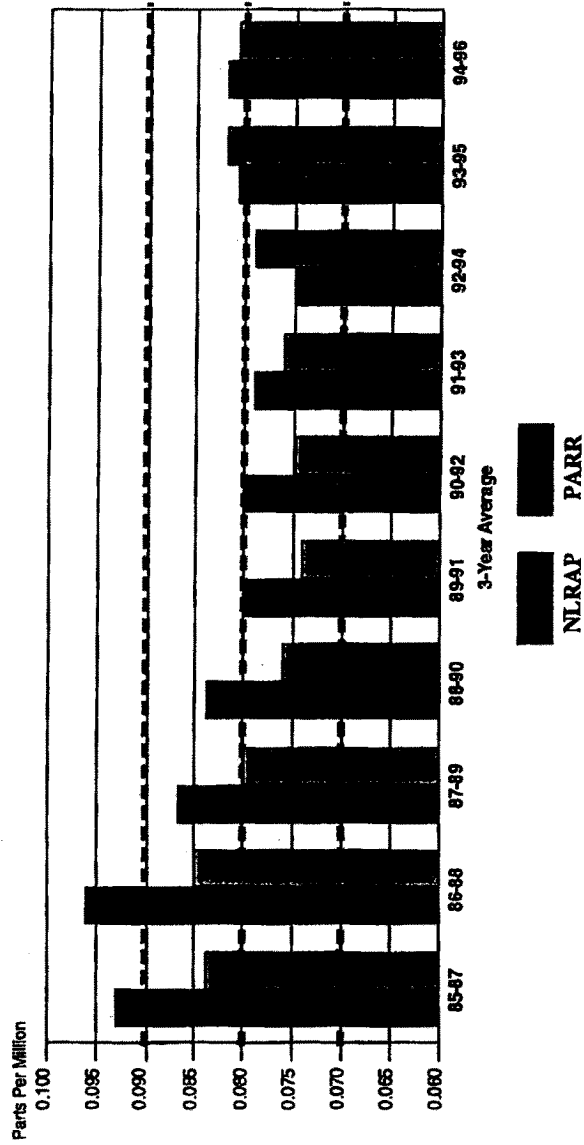
Average Annual PM-10 Values 1992 - 1995



Source: Arkansas Department
Pollution Control & Ecology

METROPLAN

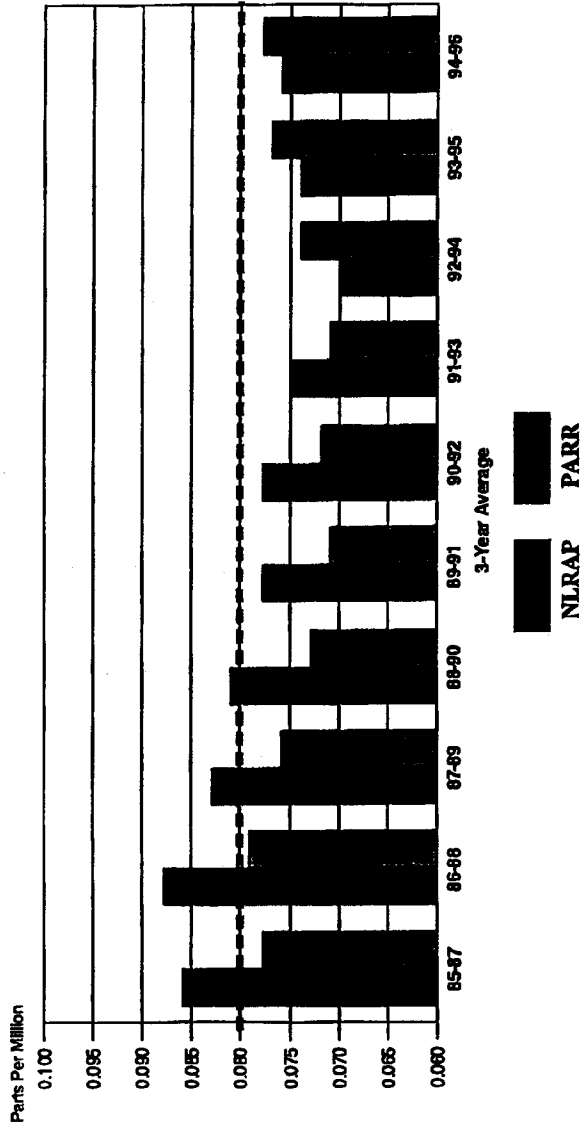
1985 - 1996 Average 3rd Highest 8-Hour Daily Maximum Ozone Concentrations



METROPLAN

Source: ADPC&E

1985 - 1996 Average 5th Highest 8-Hour Daily Maximum Ozone Concentrations



Source: ADPC&E

METROPLAN

97-214

RESOLUTION NO. 5333

A RESOLUTION URGING THE CONGRESS OF THE UNITED STATES OF AMERICA TO RETAIN EXISTING NATIONAL AMBIENT AIR QUALITY STANDARDS.

- WHEREAS, the U. S. Environmental Protection Agency has proposed new standards for ozone and particulate matter, and
- WHEREAS, these new standards could have a significant impact on local governments, substantially expanding the number of areas out of compliance with the National Ambient Air Quality Standards; and
- WHEREAS, full implementation of the existing standards for ozone has not yet been fully completed; and
- WHEREAS, EPA is proposing significant new monitoring requirements to determine whether and where there is a problem with respect to the proposed new standard for particulate matter; and
- WHEREAS, there is scientific uncertainty as to whether particulate matter (regulated at 2.5 microns) or a constituent comprising PM2.5 (sulfur dioxide, nitrogen oxide, volatile organic compounds) is a health risk; and
- WHEREAS, court-ordered deadlines to resolve issues involving complex scientific matters are inappropriate; and
- WHEREAS, because of the court ordered deadline, the comment period of these proposals will be limited to sixty days from publication in the *Federal Register*;
- NOW, THEREFORE, BE IT RESOLVED that the City of North Little Rock calls on the United States Congress to:
- reaffirm the existing standard for ozone to allow sufficient time to assess the impact of the current pollution control programs before imposing more stringent requirements;
 - overturn the court-ordered deadlines for the issuance of new standards for particulate matter; and
 - require the EPA to conduct adequate and appropriate monitoring and scientific research to assure that any new standards for particulate matter are based on sound scientific information

BE IT FURTHER RESOLVED that The City of North Little Rock urges Congress to ensure that EPA has adequate time to consider all relevant evidence in revising air standards and that the Agency not be forced to promulgate new and costly standards prematurely because of arbitrary court-ordered deadlines.

PASSED:

February 24, 1997

APPROVED:

[Signature]
Mayor Patrick H. Hays

SPONSOR:

[Signature]
Mayor Patrick H. Hays

ATTEST:

Mary L. Munnis
Mary L. Munnis, City Clerk

APPROVED AS TO FORM:

[Signature]
Randall W. Morley, City Attorney

PREPARED BY THE OFFICE OF COMMERCE AND GOVERNMENT RELATIONS

FILED 11:15 A.M. P.M.
BY Cynthia Moley
DATE 2-18-97
City Clerk's Office
North Little Rock, Ark.
Rec'd by [Signature]

STATEMENT OF GOVERNOR FRANK KEATING, OKLAHOMA, AND CHAIRMAN, INTERSTATE OIL AND GAS COMPACT COMMISSION

Mr. Chairman, thank you for the opportunity to testify on an issue that is of great importance to the citizens of Oklahoma and the Nation. The comments I make today are given on behalf of the State of Oklahoma and as chairman of the Interstate Oil and Gas Compact Commission (IOGCC), an organization representing the Governors of 29 oil and gas producing States. I have also been asked to submit the National Governors' Association viewpoints, which attached to the written portion of my testimony.

Along with the Governors of our Nation's other 49 States, I have a strong commitment to clean air standards that protect public health, and believe the needs of Americans who suffer from respiratory ailments must be addressed. At the same time, the other Governors and I recognize that the U.S. Environmental Protection Agency's current proposal on ozone and particulate matter standards would have significant costs and impact the ability of States and local officials to meet other urgent priorities. A balance must be reached between the need to protect public health and the danger of unnecessary, overly expensive regulation.

The issue before us today goes beyond whether tightening of Federal air quality standards for ozone and fine particles is necessary. I question whether the Environmental Protection Agency should impose such potentially devastating standards without providing data that clearly support the change.

The proposed change in Federal standards for ozone probably would cause Oklahoma City and Tulsa, and possibly Lawton and several other more rural areas, to fall into non-attainment with the Clean Air Act. This is despite the countless hours and millions of dollars spent by our State and local governments, businesses and citizens to comply with current Federal standards.

In fact, Oklahoma can be proud of the accomplishments we have made in cleaning the air of our State. Our Department of Environmental Quality and local entities have done an excellent job of coordinating efforts, and the progress is impressive. Our pollution level measurements statewide have declined significantly. Nationally, air pollution has declined over the past 10 years, even while the population has increased.

EPA is now seeking to enact the toughest air quality standards in our Nation's history, with enormous economic and employment consequences. Our scientists, and many scientists who advise the EPA on this matter, question whether the scientific evidence supports this proposal. Oklahoma's larger cities, which are right now competing for new businesses and industries, would find recruitment of new employers difficult or impossible with the threat of noncompliance with Federal air standards hanging over their heads. The effect on Oklahoma's largest economic contributors, including the oil and gas industry, would be profound.

Expressing a concern about inadequate time for State governments and citizens to respond to these sweeping new regulations, the Interstate Oil and Gas Compact Commission and the National Governors' Association called on the EPA to extend the public comment period on this proposal. We are pleased that the EPA responded to this request, but "back to the drawing board" might be the more appropriate response of EPA at this point.

In addition to the substantial resources States must commit to developing new State Implementation Plans for these new standards and the chilling effect on business growth and investment, communities in nonattainment of Clean Air standards would be subject to significantly increased regulations. States would be threatened with the withholding of Federal highway funds for nonattainment areas if they fail to implement regulatory action.

As Governor, I also note the lack of public demand for these new standards. The Oklahoma Department of Environmental Quality has indicated that overwhelming public support in the form of significant individual lifestyle changes and sacrifices, would be needed to help these cities attain the proposed Federal standards.

More significantly, whether these new standards would afford significant health benefits is a matter of great debate. As the Governor of this State, I care very deeply about the health of its citizens. Oklahoma's environmental experts at Department of Environmental Quality have reviewed the proposal and are concerned that the available scientific studies indicate these new standards may not offer the additional health benefits claimed by the EPA.

The EPA's research does not take into account major scientific uncertainties. The scientific community—even the EPA's own Clean Air Scientific Advisory Committee—is not in agreement as what impact, if any, fine particulate matter may have on human health at these levels of exposure. The data are weak at best.

Ozone research is another scientific “gray area.” Current ground level ozone standards—before these new standards are enacted—are already near the level at which ozone occurs naturally. Increasing these already tight standards may or may not have any benefit, and certainly would carry a heavy cost.

There are no answers from the EPA on concerns regarding the validity of the scientific basis for these proposed standards. Although the Clean Air Scientific Advisory Committee approved the documents upon which the standards are based, they were highly critical of the particulate matter scientific documents and remained neutral on the ozone documents. In fact, the committee said “There is no bright line which distinguishes any of the proposed standards as being significantly more protective of public health.”

Another element of this rush to judgment I find shocking is that nobody, outside of the researchers who performed the studies upon which EPA is basing this proposal, has apparently been given access to the raw data. His is not proper public policy.

I support measures that provide reasonable environmental and health protection, but in this case I believe the Environmental Protection Agency simply has not finished its homework. Rather than taking the stance that “we are all in this together” and using innovative non-regulatory approaches to help communities continue to achieve environmental goals—as the States have done—the EPA has adopted the familiar command-and-control approach.

A recent survey commissioned by the Competitive Enterprise Institute indicated 72 percent of the 1,000 people surveyed believe that State or local governments should determine what air pollution control measures are used. In addition, 65 percent believed that State or local government would do better at environmental protection than the Federal Government.

I agree. Since 1935 the Interstate Oil and Gas Compact Commission has acted to protect the fundamental rights of States to regulate their resources and make determinations that affect the health and safety of their citizens. Federal agency interference time and again has given us the type of environmental policy we see proposed today—short-sighted bureaucratic decisions driven by political rhetoric rather than sound science.

The chilling effect these proposed standards would have on the domestic petroleum industry would be far-reaching. These restrictions would significantly impede the ability of oil and gas producers to provide the energy the United States needs. As the majority of oil and gas operators in the IOGCC States are small business men and women, I urge Congress to carefully review EPA’s proposed standards under the new Small Business Regulatory Enforcement and Fairness Act.

Unless the Environmental Protection Agency can meet its responsibility of providing clear and compelling evidence that there is a need to impose these more stringent standards and justification for the financial burden that would result, I would stand in opposition to them.

PREPARED STATEMENT OF LIEUTENANT GOVERNOR NANCY P. HOLLISTER,
STATE OF OHIO

Mr. Chairman, members of the committee, I am Nancy Hollister, Lieutenant Governor for the State of Ohio. I appreciate the opportunity to speak to you about what I believe to be the most significant environmental policy issue facing Ohio today: U.S. EPA’s proposal to tighten the national standards for ozone and particulate matter.

First, I would like to share some background information with you about U.S. EPA’s proposal impact on Ohio and give you a sense of what our State faces if these new standards are finalized as presented. While expansion of the controversial vehicle emission testing program will probably cause the most call to elected officials, I believe it is important for this committee to understand that the ramifications of this proposal are far broader and potentially far costlier than just expanding automobile testing.

Under the Federal Clean Air Act, U.S. EPA set health-based standards for six major pollutants: sulfur dioxide, nitrogen dioxide, carbon monoxide, particulate matter, ozone and lead. The Clean Air Act requires U.S. EPA to re-evaluate these standards every 5 years. As recently as 1993, U.S. EPA announced that revisions to the ozone standard were not appropriate.

Ohio has worked hard to meet the current ozone standard. In 1993, there were four major metropolitan areas in Ohio designated as “moderate” nonattainment for ozone (Cleveland-Akron, Dayton, Cincinnati and Toledo) and three areas designated as “marginal” nonattainment (Columbus, Youngstown, and Canton). Ohio Imple-

mented an aggressive program to reduce the emissions that cause ozone, including enhanced auto emission testing in 14 counties; industrial controls; and mandatory vapor recovery systems on gasoline pump nozzles. Thanks to these and other voluntary efforts, today, only four of 88 counties in the State in the Cincinnati area remains nonattainment for ozone.

U.S. EPA's recent proposal makes the ozone standard more stringent and changes in the way we measure violations of the standard. U.S. EPA's proposal to tighten the ozone standard would send not only the seven urban areas I just mentioned back into nonattainment, but we predict that a total of at least 32 additional counties would also face nonattainment status. In fact, based on the previous 3 years readings, every single air monitor in Ohio would show exceedances of the new standard. I am the former Mayor of the city of Marietta. Marietta is located in the southeastern Ohio and has a population of 15,026 in a county with a total population of 62,254. The Ohio Environmental Protection Agency operates an ozone monitor in the city of Marietta and the monitor does not meet the proposed standards, which would mean even areas with these small populations would face nonattainment status and the subsequent control strategies. For these nonattainment areas, this would mean expansion of vehicle emission testing; mandatory clean fuels; additional controls on industries and utilities; reformulated consumer products such as paint and aerosols; and higher prices for lawn mowers and leaf blowers with cleaner burning engines. Mandatory car-pooling and restrictions on barbecue grills have also been mentioned as possible ozone control measures, but I hope we don't have the resort to that in Ohio.

Another large concern for Ohio is the effect of the nonattainment designation on industrial growth. Since virtually every urban area in Ohio will be nonattainment, the ability for these areas to attract new or expansion of existing industry will be greatly diminished. One only needs to look at the construction of many of the new automobile assembly plants in the Midwest to see that the majority were constructed in attainment areas outside of the cities further contributing to urban sprawl. U.S. EPA actions will only further accelerate the trend of urban sprawl.

The proposed Federal particulate standard is another subject of debate in Ohio. Current regulations apply to particles that are 10 microns and smaller. There are only two counties in Ohio Jefferson and Cuyahoga that don't attain the current PM_{10} standard. The existing PM_{10} standard for larger particles will still be in effect, however, this rulemaking actually relaxes the PM_{10} standard. In addition, U.S. EPA is proposing to create a standard that will regulate a new pollutant very fine particles known as $PM_{2.5}$.

Unfortunately, I can't offer the same details about the scope of the nonattainment area for $PM_{2.5}$. There is no State or national air monitoring network for $PM_{2.5}$. U.S. EPA estimated that 21 Ohio counties would not attain the standard for the finer particulates. And if you're thinking that only urban areas would be affected, listen to some of the counties on U.S. EPA's list for particulates: Noble County, with a population of about 11,000; Wyandot County, population 22,000; and Sandusky County, population 62,000. Quiet honestly, we have no idea how U.S. EPA came up with that list; we do know they admit that the list is subject to "significant uncertainty."

It is possible that many of the control programs we would implement to comply with the new ozone standard could help with meeting the fine particulate standard. It appears that coal-fired utilities may be affected the most, but because we know so little about the makeup of $PM_{2.5}$, we may have to start regulating a universe of activities that we haven't even considered yet. However, all activities that contribute to the generation of fine dust are potential sources needing control including road dust, woodburning fireplaces, agricultural activities and virtually all manufacturing processes. Our preliminary estimate is that compliance cost for the new particulate standard will be on the order of \$2 billion.

U.S. EPA's decision to combine the ozone and particulate standard review into one rulemaking is significant. While we believe there are problems with the scientific basis behind the changes to both standards, U.S. EPA's own documents show that the costs of meeting the new ozone standard may exceed the benefits expected. U.S. EPA appears to be relying on benefits from the new particulate standard to justify the cost of the ozone standard. Not only do I believe that U.S. EPA seriously underestimated the cost of attaining both standards, but our review of this proposal raises serious doubts about the projected health benefits.

Let me briefly explain the problems we've identified with each proposed standard. I'll start with ozone. We agree with U.S. EPA's science advisors that the more stringent ozone standard will not significantly improve public health. One of the principle health studies that U.S. EPA used to calculate health benefits found that if compliance with the proposed ozone standard is achieved, there would be a reduc-

tion of less than 1 percent in the hospital visits per year in the New York City area for asthma related illnesses.

Furthermore, U.S. EPA recognizes that some area in this country have been unable to achieve the existing ozone standard and still more areas would find it impossible to achieve the new standard. In fact, EPA estimates that 53 million people would end up living in areas where attaining the new ozone standard and thus realizing all of the health benefits would be virtually impossible. We believe that it may be even worse: even more areas than projected won't be able to comply with the ozone standard. We would need a major program to control emissions for utilities and other combustion sources through the entire eastern United States, and Ohio would have to implement every conceivable control measure from enhanced automobile testing to controls on industry and more expensive fuels. Even then, many of Ohio's urban areas may not be able to attain the proposed ozone standard.

While my primary concern with U.S. EPA's proposed ozone standard is the lack of public health benefit, I also want to draw your attention to plans in U.S. EPA's cost estimates. U.S. EPA estimated the national cost of partial attainment to be as much as \$.6 billion annually. However, U.S. EPA assumed that States like Ohio would already be spending billions of dollars in new controls to help the Northeast States in the Ozone Transport Commission to meet the existing ozone standard, so the costs of those controls were not included in the estimate for the revised ozone standard. We estimate the cost for Ohio, alone, for partial attainment to be \$.76 billion per year.

I also wanted to address direct cost to State and local government of U.S. EPA's proposal. There are many universities, health and correctional facilities that burn coal in boilers to supply heat or power. In Ohio, we estimate that there are approximately 13 such facilities with 34 boilers that would be subject to the new standards. Under the U.S. EPA proposal for ozone, it is likely that nitrogen oxides emissions will need to be reduced. For fine particulate, increased collection of particulate matter will be necessary. For this type of installation, we estimate the capital cost for a typical facility to be \$700,000, not including operating cost. Although faced with these additional costs, many facilities will choose to convert to higher priced natural gas. This wastes valuable capital that was expended on the original installation and will increase operating costs. These are real costs that will be expended on additional controls instead of these resources being directed to the main function of these institutions.

Let me now turn to the particulate standard. I can summarize my concerns about U.S. EPA's proposal to create a fine particulate standard with three words: lack of data. As I mentioned earlier, U.S. EPA is relying on projected health benefits of the proposed particulate standard to justify the cost of both standards. There have been a number of scientific studies which show a link between air pollution and significant respiratory and cardiovascular-related effects. However, U.S. EPA has not been able to establish a direct link between fine particulate and those health problems. I am concerned that we may spend billions of dollars to comply with a new particulate standard in Ohio only to find after more scientific research that we were going after the wrong pollutant. The public soon loses faith in government's credibility when public health scares turn out to be unjustified. Even U.S. EPA recognizes the need for more research for particulate matter. The President's budget for Federal fiscal year 1998 requests \$26.4 million, a 37 percent increase, to fund studies to determine the link between particulate matter and health effects. This request is indicative to the weakness of the current proposal and that U.S. EPA should await the results of this effort before promulgating a new standard. I would urge U.S. EPA to develop a comprehensive program that includes further scientific research on health effects, additional monitoring of air quality and allow for adequate time for public review and comment on the health effects research before proceeding with a change to this standard.

I hope I have given you sense of the problem we see with U.S. EPA's proposal. I would like to conclude with some thoughts about immediate and long-term solutions to improving the air quality standard setting process in this country.

The short-term problem is that U.S. EPA gave interested parties only 60 days to comment on this proposal. Ohio did all it could to fully understand the impact of this rule, but 60 days is just not enough time to thoroughly review more than 1,000 pages of rules plus thousand of technical supporting documents. Governor George Voinovich of Ohio and a number of other elected officials requests additional time to review the proposal, and U.S. EPA requested from the Federal court with jurisdiction over this case for the additional time. Unfortunately, the judge only allowed an additional 21 days, which remains an insufficient time. Many of Ohio's State departments are preparing formal responses to U.S. EPA's dockets on this matter. When they are finalized, I would also like to submit a set to your record.

In the long run, I believe States will find relief only through congressional action. William Ruckelshaus, a former U.S. EPA Administration official, has said the Clean Air Act created "an impossible standard of perfection." I do not advocate a rollback of the public health protections many of our environmental laws have produced. However, 30 years of science and experience has taught us that a "zero risk" standard is not possible. The Clean Air Act needs to be updated to reflect this knowledge and to create a regulatory system which maximizes public resources for maximum public benefit.

In addition to developing more reasonable goals for setting clean air standards, Congress also needs to incorporate a requirement that a comprehensive, cost-benefit analysis be made part of the standard setting process. Today, the Clean Air Act does not allow U.S. EPA to consider cost when setting standards. The only reason U.S. EPA has done any type of cost benefit analysis with this rulemaking is because Congress passed the Small Business Regulatory Enforcement and Fairness Act last year requiring such an analysis on major rules which affect small businesses. By U.S. EPA's own estimate, the cost of compliance with these standards is on the order of \$6-8 billion a year. That raises the estimated cost of the entire Clean Air Act Amendments of 1990 by almost a third.

I would be happy to answer any questions you may have. Thank you.

PREPARED STATEMENT OF MAYOR M. SUSAN SAVAGE, TULSA, OK

Thank you for this opportunity to address the Senate Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety today. I am here to speak on behalf of the Nation's mayors and especially as chair of the Energy and Environment Committee for the U.S. Conference of Mayors.

The primary responsibility of a mayor is to protect the public health and safety of the citizens in our communities. However, proposed new air quality standards encompass far more than just a debate about the levels of ozone and particulate matter that we will determine to be acceptable in our air. The outcome of this discussion will speak volumes about the livability of our cities well into the future.

Clean air is a laudable, responsible goal. Governments, industry, and citizens have an obligation to ensure that the air we breathe is clean and safe across this country. Yet, the discussion of the proposed new air quality standards is being held in isolation from the discussion of any implementation plans for the new standard. Will communities be held to a more severe standard for the pollution which originates in and is transported from other areas? Will communities be held responsible for the hydrocarbon emissions of those automobiles driving into or through an urban area on a daily or periodic basis? How can communities mitigate the effects of unfavorable weather patterns which contribute to the ozone levels due to high temperatures or a lack of wind?

This discussion of the proposed new air quality standards is being held without consideration of the significant and substantial policy decisions this committee will face this year in its deliberations on the reauthorization of ISTEA, Brownfields, Superfund, the future of Congestion Mitigation Air Quality funds and other significant environmental policy issues which dramatically impact the liveability of cities and for which well coordinated policy goals need to be articulated and pursued.

Talk to any mayor of any sized city and what you hear is the same—years of federally imposed mandates to meet uniformly applied environmental standards have contributed to urban sprawl, creating a greater reliance upon the automobile while at the same time, reductions in public transit operating dollars and the proposed elimination of the Congestion Mitigation Air Quality funds remove essential tools for communities who work to improve air quality.

In fact, cities like Tulsa, which has made enormous strides toward cleaner air and remained in compliance with air quality standards, are penalized by receiving fewer CMAQ dollars than other cities which have not taken proactive positions and find themselves in non-attainment.

Mayors across the country whose cities are currently in attainment and who I have worked to maintain that status, need to understand the purpose and the value of being redesignated into non-attainment. It is unclear how this causes an improvement in air quality. A health benefit analysis is the basis for the recommendation to change the standard, yet the lack of inclusion of an implementation strategy, no commitment to adequate funding for impacted communities, and definitive knowledge about the precursors of ozone impede progress toward the creation of effective, local responses.

Other pressing matters need to be addressed, even if the rules for implementation evolve subsequent to the promulgation of the standard. As a group of diverse com-

munities, we question the wisdom of putting the two standards, ozone and particulate matter in the same category. While their effects may be similar in the health based data, the available technology to monitor the two pollutants is vastly different. The country is ill-prepared to monitor for .25 particulate matter since few monitors exist. Additionally, there are no guidelines for their placement and evaluation, leaving community leaders unable to construct a workable strategy.

In the materials released from the Environmental Protection Agency there has been mention of development and implementation of innovative technologies. Cities are interested in being part of any initiative which involves new technology. At the same time we would like to see the Agency acknowledge and credit some of the effective pollution reduction methods which use little or no technology but are based on public awareness and leadership commitment.

Have other measures to improve air quality been examined as we as a Nation strive to improve air quality? Does the focus on a more difficult standard provide the impetus needed to generate the public and private support needed to provide a desirable air quality? We encourage further research to explain the origin of the precursors for ozone. The sources of background ozone, which come from biogenic sources, will seriously affect any community's mitigation strategies.

The definition of nonattainment and its implications is another issue we would like to explore further. With the prospect of so many potential new nonattainment areas, there exists the possibility to create new locally designed programs and strategies without adding the burden of punitive economic measures. Nonattainment could be a measure at which further implementation begins; it need not be not a threat to economic development. Incentives, rather than punitive measures ought to be afforded to communities and industries which produce and burn cleaner fuels.

Tulsa is ready to use the new health advisory system described by EPA to encourage at risk individuals to stay indoors when high ozone is anticipated. Our Ozone Alert! alternate commute program is premised on the availability of information reaching 250 large companies before 4 p.m. on the day before the air quality is predicted to be poor. That information network is augmented by media announcements which begin during the afternoon commute and are carried on television in the evening. The addition of specific pollution information would be very little extra trouble and provide a most beneficial service. This service should be included in a State Implementation Plan.

In Tulsa, we created the Nation's first Flexible Attainment Region or FAR in partnership with the EPA. The FAR allows an area to custom-design programs to improve air quality when there is a violation of the standard and to add more measures as they are necessary without redesignation to nonattainment. These partnerships should be encouraged to ensure local responses to air quality concerns. Local leaders are best positioned to make the decisions which work in their communities.

Mayors care deeply about the health and safety of their citizens. We believe that we can work cooperatively with State and Federal officials to find the best strategies to improve air quality for all Americans.

PREPARED STATEMENT OF STATE SENATOR PAUL MUEGGE, OKLAHOMA, ON BEHALF OF
THE NATIONAL CONFERENCE OF STATE LEGISLATURES

NCSL is a strong supporter of the principles underlying the Clean Air Act. NCSL repeatedly and forcefully asserts that the U.S. Environmental Protection Agency (EPA) should work with State and local officials to implement and maintain an environmentally sensitive and cost-effective clean air policy. Setting minimum national ambient air quality standards that protect human health and preserve the environment should be a top priority.

While advocating clean air policy, NCSL also vehemently supports the Unfunded Mandates Reform Act and Executive Orders 12866 and 12875. NCSL has serious concerns about the failure of EPA to comply with the Unfunded Mandates Law and the executive orders during the rulemaking process to revise the air quality standards for particulate matter and ozone. Clearly, Congress and the President intended EPA to comply with these policies by considering cost during all rulemaking actions.

NCSL asserts that EPA is required to adhere to the following provisions of the Unfunded Mandates Law and Executive Orders 12866 and 12875:

1. EPA is required to assess the full cost of State and local compliance with the revised standards.
2. EPA is required to disclose all Federal resources available to States for compliance activities.
3. EPA is required to assess alternatives and select the least burdensome and most cost-effective option.

4. EPA is required to work with elected State and local officials during promulgation of the standards.

In addition, NCSL makes the following points regarding EPA's regulatory action to revise the National Ambient Air Quality Standards for particulate matter and ozone:

1. Section 105 of the Clean Air Act is the main source of Federal assistance for State air quality programs, including implementation of new air quality standards. Section 105 authorizes State grants that may cover up to three-fifths of the cost of implementing State plans. Because EPA determined that the proposed rules are "significant regulatory actions," meaning that the total annual cost of compliance will be in excess of \$100 million, EPA must explain why its budget request for Section 105 grants for fiscal year 1998 was only \$157 million, merely \$4 million more than estimated fiscal year 1997 outlays.

2. EPA must demonstrate to the satisfaction of Federal, State and local officials as well as to the public that revised standards are necessary and that the new standards will provide the utmost protection of public health and the environment. NCSL fears that the controversy surrounding the revisions may arouse enough public opposition to ultimately reverse EPA's decision. If the revisions are rescinded after finalization, States may have begun to comply by entering into contractual and financial commitments. It would be difficult and expensive for States to withdraw from such commitments.

To clarify, NCSL has expertise on the *rulemaking process*. NCSL does not possess the scientific or technical expertise required to determine "unhealthy" levels of ambient ozone and particulate matter. Therefore, NCSL believes it would be imprudent to make educated, but not expert, guesses regarding the support for or opposition to the standards contained in the proposed rules.

Mr. Chairman and members of the subcommittee, I am Senator Paul Muegge from the State of Oklahoma testifying before you on behalf of the National Conference of State Legislatures. I appreciate the opportunity to join you today to discuss the proposed changes to the National Ambient Air Quality Standards for particulate matter and ozone.

The National Conference of State Legislatures (NCSL) is the bipartisan organization that represents the nation's 7,541 State legislators. We assess Federal legislation and regulation to ensure that State and Federal responsibilities are appropriately sorted out. We further work to remove impediments to successful implementation of Federal law and regulation. Also, NCSL serves as the key resource for State lawmakers for information and analysis of Federal legislative and regulatory actions on environmental and other issues.

NCSL is a strong supporter of the principles underlying the Clean Air Act Amendments of 1990. NCSL has repeatedly and forcefully stated its view that the Federal Government should implement and maintain an environmentally sensitive and cost-effective clean air policy that establishes minimum national ambient air quality standards in cooperation and consultation with State and local governments.

NCSL supports minimum Federal standards for ambient particulate matter and ozone. Protection of human health and preservation of the environment are a top priority for States. NCSL urges EPA to proceed diligently with full implementation of the Clean Air Act to achieve healthy air quality for the public and the environment. Specifically, NCSL believes that both stationary and mobile sources must reduce emissions of ozone and particulate matter precursors, nitrogen oxide (NO_x) and volatile organic compound (VOC).

NCSL does not possess the scientific or technical expertise required to evaluate and comment on the specific standards set out in the proposed rules. NCSL believes it would be imprudent to make educated, but not expert, guesses regarding the support or opposition to the proposed standards.

However, NCSL has serious concerns related to the *process* of promulgation of the proposed rules to revise the standards for ozone and particulate matter. The concerns result largely from the failure of the U.S. Environmental Protection Agency (EPA) to comply with Federal law and Presidential executive orders on unfunded mandate relief. The concerns do not focus on the new standards or the underlying science that is the basis for the new standards. NCSL refrains from commenting on the content of the proposed rules for new particulate matter standards and revised ozone standards.

My testimony will focus solely on the *process* by which EPA developed the rules and its failure to comply with provisions of the Unfunded Mandate Reform Act of 1995 and two Presidential executive orders. NCSL asserts that in order to adhere

to provisions of the Unfunded Mandates Law and Executive Orders 12866 and 12875, EPA is required to:

1. Assess the full cost of State compliance with the revised standards.
2. Disclose all Federal resources available to States for compliance activities.
3. Identify and assess all alternatives to the proposed revisions and select the least burdensome and most cost-effective option.
4. Consult and work closely with State and local governments during promulgation and implementation of the revised standards.
5. Provide full Federal funding and complete guidance for State implementation.
6. Publish detailed explanations of the reasons for revising the standards.

NCSL makes these recommendations as an organization with a commitment to the Clean Air Act. NCSL believes the Clean Air Act Amendments of 1990 address important air quality issues and are essential to protecting public health and the environment. At the same time, in order to meet the goals of the Clean Air Act, Congress and the EPA must fulfill their responsibilities to provide financial and technical assistance to States. Moreover, EPA has a legal and ethical obligation to meet the requirements of UMRA and Executive Orders 12866 and 12875.

THE UNFUNDED MANDATE REFORM ACT OF 1995

The Unfunded Mandate Reform Act (UMRA) is a historic piece of legislation that recognizes the threat to our constitutional system of federalism represented by Federal legislation that imposes costs and requirements on State and local governments without regard to their ability to comply. Among others, the purposes of the Act are “to promote informed and deliberate decisions, by Congress on the appropriateness of Federal mandates in any particular instance.”

EPA is obligated by law to adhere to UMRA during promulgation of revisions to ozone and particulate matter standards. With the enactment of UMRA, Congress promised States relief from the burden of unfunded mandates and further promised States that Federal agencies would work cooperatively with them to develop regulatory alternatives that are less expensive and more cost-effective. Congress understood that Federal mandate relief efforts will preserve the financial viability of State governments, thus ensuring successful implementation of Federal laws and regulations.

Title II of UMRA requires Federal agencies to prepare and consider estimates of the budgetary impact of regulations containing unfunded Federal mandates on State, local and tribal governments, unless otherwise prohibited by Federal law. Congress imposed this requirement on Federal agencies in order to generate the data necessary for informed congressional decisions on regulatory and appropriations issues. NCSL believes that the aggregate economic burden of the proposed air quality standards are great enough to trigger further congressional action to reduce the burden on the States, either by increasing appropriations or relieving regulatory burdens. Furthermore, UMRA requires EPA to generate estimates of mandate costs in order to develop less burdensome regulatory alternatives.

EXECUTIVE ORDERS 12866 AND 12875

President Clinton issued Executive Order 12866 “Regulatory Planning and Review” in September, 1993, in response to States’ concern of being overwhelmed by the cumulative effect of unfunded mandates. The intent of 12866 is to establish “a regulatory system that protects and improves health, safety, and well-being of the American public and the environment, and improves the performance of the economy without imposing unacceptable or unreasonable costs on society.”

The President issued Executive Order 12875 “Enhancing the Intergovernmental Partnership” in October 1993 as a supplement to 12866. Under 12875, Federal agencies are specifically directed to reduce unfunded mandates on State, local and tribal governments and increase their flexibility in complying with Federal regulations.

The orders demonstrate the Administration’s commitment to relieving the economic burden of unfunded Federal mandates on the States. Though EPA partially complied with Executive Order 12866 by submitting information to OMB, EPA has an obligation to fully comply with Executive Orders 12866 and 12875 by adopting the most cost-effective options when promulgating the proposed changes to the national air quality standards for ozone and particulate matter.

In response to the proposed changes to the national ambient air quality standard for particulate matter and ozone, NCSL asserts that EPA is required to strictly adhere to the following provisions of UMRA and Executive Orders 12866 and 12875:

1. *EPA must assess the full cost of State and local compliance with regulatory actions to revise the national ambient air quality standards for particulate matter and ozone. [UMRA Section 201 and Executive Order 12866 Section 1(b)(3)]*

UMRA and Executive Order 12866 require EPA to estimate the aggregate economic impact that the revised standards will have on State, local and tribal governments. If the estimated aggregate annual expenditures of the rule is \$100 million or more, the rule is considered a "significant regulatory action" that triggers requirements to complete and publish with the rule the following in-depth analysis:

1. Qualitative and quantitative assessment of the anticipated costs and benefits of the mandate;
2. Analysis of Federal financial assistance and other Federal resources available to State, local, and tribal governments;
3. Estimates of future compliance costs;
4. Analysis of any disproportionate budgetary effects on any regions, States, localities and tribes;
5. Estimates of the effects on the national economy;
6. Reports of EPA's prior consultation with elected State, local and tribal officials;
7. Summary of submitted comments from the various levels of government; and
8. EPA's evaluation of those comments.

EPA produced regulatory impact analyses, pursuant to Executive Order 12866, that assess the costs, economic impacts and benefits associated with implementation of the revised standards. Though the revised standards are "significant regulatory actions," EPA claims, in the regulatory impact section of the proposed rules, that it does not have to comply with UMRA because "it is inconsistent with applicable law." EPA has failed to produce most of the required in-depth analyses listed above, specifically numbers two through eight, and failed to publish, as part of the proposed rule in the Federal Register, any of the analyses.

Estimates of how much money State, local and tribal governments will need to spend to comply with the revised air quality standards are critical. The President of the United States as well as Members of Congress have a need to know how much the revised standards will cost the States in order to make informed executive and legislative decisions regarding, not merely the Clean Air Act, but also the imposition of new mandates in other areas. Decisions by the President and Congress pertaining to funding of current and future mandates depend on accurate information from Federal agencies regarding the financial burden on States and localities.

EPA's estimate must contain all costs associated with changing the air quality standards. This estimate should account for the costs of enactment of State authorizing legislation, promulgation of State regulations, development of new State air quality plans, construction of pollution control measures, and installation of monitoring stations.

Furthermore, estimates must account for the new, more stringent air quality programs that would be required in many States. Many areas have already employed efficient and effective air pollution control measures, such as HOV lanes and public transportation programs. In an attempt to reduce pollution levels even lower, some States may have to use expensive, inefficient, and potentially unpopular measures, such as the employer commute option program.

2. *EPA must disclose all Federal resources available to State and local governments that may be used to cover the cost of implementing and achieving the revised standards. [UMRA Section 202]*

UMRA requires EPA to disclose all Federal funding and other resources available to States for implementation of the revised standards. Executive Order 12875 Section 1(a) takes this concept one step further by prohibiting EPA from imposing new standards that are not required by law unless there are Federal funds available to cover the costs or, EPA can submit to OMB documentation of consultation with State officials and data supporting the need for the mandate. According to both proposed rules, EPA submitted documentation to OMB in partial compliance with Executive Order 12866, but neither rule contained notice of EPA compliance with Executive Order 12875. Again, NCSL asserts that EPA must fully comply with both Executive Orders 12866 and 12875.

3. *EPA must select the least burdensome and most cost-effective option that will achieve the same level of public health protection. [UMRA Section 205 and Executive Order 12866 Section 1(b)(3) and Section 1(b)(6)]*

UMRA and Executive Order 12866 require EPA to assess and consider all options and to adopt the least expensive and most cost-effective alternative for achieving the intended goal of the proposed rules. In addition, Executive Order 12866 requires EPA to prepare a cost-benefit analysis to demonstrate that the benefits justify the

costs of the proposed rule. NCSL asserts that EPA's failure to consider cost during the proposed rulemaking process was in violation of UMRA and both Executive Orders. Congress and the President clearly intended to require EPA to consider cost issues and implementation problems when setting revised standards.

NCSL disputes claims by EPA that it is prohibited from considering the cost of attaining revised national air quality standards. UMRA requires Federal agencies, including the EPA, to assess the economic impact of their regulatory actions on State, local and tribal governments, as well as the private sector. Absent a clear statement by Congress that it intended to exempt Clean Air Act regulations from the coverage of the Unfunded Mandates Reform Act, the EPA may not presume that it is prohibited from considering the cost of attaining revised national ambient air quality standards. UMRA, Title I, Section 4 clearly lists the categories of Federal law that are excluded from its coverage. The Clean Air Act is not one of the listed exclusions.

Furthermore, NCSL challenges EPA's assertion in testimony before the Senate Committee on Environment and Public Works that actions during the *public health phase* are completely independent from actions during the *implementation phase*. NCSL also disputes EPA's claim that the revised standards, in themselves, would not impose any additional cost or mandates. NCSL strongly believes that the chosen standard closely relates to the cost of implementation. Because the cost varies for different standards, NCSL asserts that the EPA must fully comply with UMRA and Executive Order 12866 by considering cost when adopting revised standards. Furthermore, EPA must adopt standards that are more cost-effective, more attainable, more acceptable to the public and more likely to be implemented successfully.

4. *EPA must furnish State legislators with opportunities to provide meaningful input during development and implementation of any changes to the national ambient air quality standards. [UMRA, Sec. 204; Executive Order 12866, Sec. 1(b)(9); and Executive Order 12875, Sec. 1(b)]*

UMRA and Executive Orders 12866 and 12875 require EPA to consult and work with State legislators to reach a mutual understanding about how to further improve air quality without imposing such burdensome costs or unpopular control measures that the process breaks down. NCSL lauds EPA's coordination of the Clean Air Act Advisory Committee to fulfill this intergovernmental dialog requirement. Listed among the members of the committee was a State senator from Maryland. NCSL understands that the State senator participates in advisory committee meetings and is content with the efforts that EPA is making to continue regular dialog with the advisory committee.

Though EPA has fulfilled this obligation to date, NCSL would like to stress the importance and legal obligation of EPA to continue working with State legislators during promulgation of the revised standards. State legislators must draft, consider and enact enabling legislation to authorize new or amended State programs, including those required by Federal law or regulation. Without enabling legislation, State agencies have no authority to administer State programs. In addition, State legislators are solely responsible for appropriating State funds that pay for State programs. State legislators, therefore, must not be dictated to, but rather must be made full partners in the process of defining and implementing mutual goals.

The States have a wealth of experience in implementing control programs. State legislators, similarly, have expertise in crafting environmental programs in ways that are sensitive to local values and conditions. NCSL encourages Congress and the EPA to pay particular attention to the voices of that expertise and experience. EPA should establish a regular process for communication with State legislators and should develop a working group of legislators to become more actively involved in the implementation process.

In addition to specific provisions discussed above, UMRA and Executive Orders 12866 and 12875 contain overall principles that Federal agencies should follow during promulgation of Federal regulations that impose unfunded mandates on States. NCSL asserts that EPA should adhere to those principles as follows:

5. *EPA should provide full Federal funding, complete technical guidance and maximum flexibility to States for compliance with the revised standards.*

The imposition of new air quality standards without additional Federal funds contradicts the commitment of the Administration and Congress to reduce the burden of unfunded mandates on States. NCSL believes that States must have full financial and complete technical assistance to ensure attainment of the new standards, and to cover in part the cost of new mandates on States.

NCSL understands that Clean Air Act, Section 105 is the main source of Federal assistance for State air quality programs, including implementation of new national

ambient air quality standards. Section 105 authorizes EPA to provide States with grants that cover up to three-fifths of the cost of implementing State plans. Because EPA determined that the proposed rules are "significant regulatory actions," meaning that the total annual cost of compliance will be in excess of \$100 million each, NCSL seeks an explanation of why the budget request by EPA for Section 105 grants for fiscal year 1998 was only \$157 million, merely \$4 million more than estimated fiscal year 1997 outlays. According to EPA estimates, \$4 million in additional funding will not be enough to cover the costs associated with these revised regulations.

If EPA imposes new standards for ozone and particulate matter without providing accompanying financial and technical assistance, States will face a significant financial burden. If the challenge presented by this unfunded mandate burden cannot be met, States may face expensive and economically restrictive offset sanctions. The sanctioned area would experience additional economic hardship caused by the need to offset any new emission sources by twice as much reduction in other sources. This has the potential to significantly stunt economic growth. The depressive effects on local economies coupled with increasing cost of compliance may accelerate a downward spiral of non-compliance. Widespread non-compliance may undermine public support for the Clean Air Act and breed increased public cynicism about the government's ability to effectively administer programs.

6. EPA should publish detailed explanations of why the specific revisions are necessary and provide scientific evidence to support the estimated benefits to public health.

EPA must demonstrate to the satisfaction of Federal, State and local officials as well as to the public that revised standards are necessary and that the new standards will increase protection of public health and the environment. NCSL fears that the controversy surrounding the revisions may arouse enough public opposition to ultimately reverse EPA's decision. If the revisions are rescinded after finalization, States may have entered into commitments, such as purchasing testing equipment or contracting for more public transit. It would be difficult and expensive for States to withdraw from contracts if the final revisions are rescinded.

In recent years, there have been cases where EPA has imposed a mandate on regulated entities and then, after a public outcry, retracted the mandate. In some cases, the regulated entities had complied with the mandate by entering into contractual and financial commitments based on the imposed mandate. These regulated entities were left with few options once the mandate had been rescinded: either pay large penalties to withdraw from legal and financial commitments or contend with an outraged public.

A classic example of this problem, as discussed above, is the mandate that required States to include IM-240 testing equipment as part of the enhanced inspection and maintenance program. Some States complied by including this technology in their air quality plan. These States bought land and financially committed to buy the expensive IM-240 equipment. Public opposition, fueled by expectations of long lines and costly inspections, convinced many States and finally the EPA to abandon the costly testing equipment. States now have the flexibility to choose the most efficient and effective technology for their enhanced inspection and maintenance program.

Rather than repeat the IM-240 fiasco, EPA is better advised to comply with UMRA and Executive Orders 12866 and 12875 in order to deal upfront with the cost and implementation problems.

Once again, NCSL asserts that EPA is required to strictly adhere to the provisions and principles of UMRA and Executive Orders 12866 and 12875 while promulgating revisions to the national ambient air quality standard for particulate matter and ozone. Clearly Congress and the President intended EPA to comply with these edicts by estimating and considering cost during its rulemaking actions. The burden of unfunded mandates on State, local and tribal government has become too great. Congress and the President recognized the looming threat of rampant unfunded mandates and have directed Federal agencies to ameliorate the problem.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to share the views of the National Conference of State Legislatures regarding the proposed revisions to the National Ambient Air Quality Standards for particulate matter and ozone.

PREPARED STATEMENT OF MARK SCHWARTZ, COUNCILMEMBER, OKLAHOMA CITY, OK

Mr. Chairman, members of the Subcommittee: I am Mark Schwartz, Councilmember from Oklahoma City and President of the National League of Cities.

I am here today to testify on behalf of NLC and the 16,000 cities and towns across the Nation we represent on EPA'S proposed new standards for ozone and particulate matter. I would like to ask if I may submit, for the record, a copy of NLC's resolution on the proposed changes to the National Ambient Air Quality Standards adopted last December at our annual meeting.

Municipal elected officials support Federal initiatives designed to protect public health and the environment. NLC was an active and supportive participant in the debate on, and enactment of, the 1990 Clean Air Act Amendments. As local elected officials we care about our communities and the people—including our own families—who live there. We are not solely discussing economic development and attracting industry and jobs. None of us want to be out of compliance with Federal standards. We want to be able to assure our citizens that the air they breathe, the water they drink, and the rivers, lakes and streams in which they play, meet the highest and safest possible public health standards. And, local governments are willing to make every effort possible to obtain the necessary resources to achieve these objectives. We, as local elected officials can bring little to the smog and soot debate as scientists or epidemiologists. So while we cannot challenge with impeccable credentials the adequacy of the science on which these proposed new standards are based, we do believe we have the appropriate standing to raise significant concerns about the process by which they were developed and are being proposed, as well as the potential for imposing exceedingly costly new Federal mandates on the citizens of this country that may yield few, if any, benefits.

From the municipal perspective, there are four areas of concern:

- credibility as to
 - the current air quality standards, and
 - the adequacy of the science on which requirements are based;
 - continued public financial support for Clean Air Act initiatives
- inconsistency among statutes that have overlapping impacts;
- unattainable objectives; and,
- a process—or lack of one—that fosters unhelpful judicial interventions.

CREDIBILITY

Current NAAQS

Many of the State Implementation Plans developed as a result of the 1990 Clean Air Act Amendments are just now being implemented. The implementation strategies incorporated in these plans have not been in effect long enough to determine their impact. We need answers to questions about the validity and impacts of the requirements now imposed on our States, local governments, and businesses if yet another set of requirements will overlay the existing ones. The implication—at least for the uninitiated—is that what is currently being required is meaningless or futile. If significant additional resources are to be committed to further reductions in pollutants, there must also be adequate assurances that these investments will yield (at a minimum) commensurate, or (at a maximum) appreciable health benefits.

We are also troubled by the absence of adequate and basic information with respect to PM_{2.5}. It would seem appropriate to us that before issuing a new set of requirements, it might be helpful to know where it is a problem, the pervasiveness of the problem and, whether it is the pollutant or a subset of the pollutant that is the cause of the problem.

Science

It is clear from recent reporting, and from testimony given at your recent hearings, that there is significant disagreement about the adequacy of the science on which the proposed new standards are based. While we might agree with Administrator Browner that demonstrable “cause and effect” justifies action, the very existence of the scientific controversy raises questions in our minds about whether the “cause and effect” are indeed sufficiently certain to justify action. We find it inexplicable that as the Nation's air quality improves, the incidence and/or severity of asthma increases. Logic would indicate it should be the reverse. We are concerned that we may be moving toward requirements to regulate naturally occurring phenomena, such as wind-borne sand from beaches and deserts, or pollen from natural vegetation.

Public Support

With respect to continued public support, many municipalities have made Herculean efforts to come into compliance with the National Ambient Air Quality Standards. To learn now that instead of some recognition of accomplishment, these efforts were inadequate, inappropriate, or ineffective is dismaying.

As you well know, many States and even more local governments face voter imposed constraints on our ability to raise revenues. Sooner or later our constituents will object to financing the implementation of Federal mandates designed to accomplish specific objectives if, after the fact, these investments prove to be futile. It is not just our credibility that is at stake; the Federal Government has a similar interest in assuring the wise use of our limited resources.

INCONSISTENCY

Your committee was responsive to NLC's concerns about the inconsistencies between requirements in the Clean Air Act (required *reductions* in vehicle miles traveled) and provisions in the highway legislation in effect at the time which allocated resources based on *increases* in VMTs. In developing and enacting the Intermodal Surface Transportation Efficiency Act (ISTEA), these conflicting objectives were addressed. Now we are faced with an Administration seeking to impose more stringent controls on emissions causing air pollution—many of which are generated by stop/go rush hour traffic—while simultaneously proposing significant cuts in transit funding which provides a virtually guaranteed method for reducing the proximate cause of these self-same pollutants! Equally seriously, many in Congress are proposing changes to ISTEA which would remove the Congestion Mitigation Air Quality program. That is but one inconsistency.

Another example: the Nation's larger municipalities—and soon the preponderance of all other cities, towns and counties—are, or will be, required to comply with stormwater management measures to prevent, eliminate or reduce pollutants in urban run-off. One method to accomplish this objective is street sweeping. Will clean air requirements prevent municipalities from implementing such activities because street sweeping raises air-borne dust, thus reducing their ability to meet the Federal stormwater mandate?

UNATTAINABLE OBJECTIVES

One of our major concerns is the increasing intrusion of the Federal Government into decisions with respect to local land use planning, and the distinctly anti-growth bias of many Federal environmental mandates. Less than 10 percent of the land area of this Nation is urbanized; our population is growing at a reasonable pace of about 1 percent per year. If we can neither build housing, office space, industrial facilities in undeveloped areas, nor restore or rehabilitate such facilities in developed areas, how do we accommodate our growing population? Environmental mandates are not, nor should they be, the means for determining national growth policy. If we, as a Nation, are ready to abandon the restoration and revitalization of our cities, or to control population growth, that should be attained openly and honestly.

Municipal officials are also concerned about being required to comply with Federal standards when there are few or no tools available to attain such compliance or when there is no body of knowledge about how to achieve compliance. This committee addressed many these concerns in the 1990 Clean Air Act Amendments by creating classes of nonattainment based on the severity of the air pollution problem, alternative requirements based on the degree of pollution, and varying timeframes for attaining compliance based on the complexity of the problems being addressed.

Nonattainment designations based on severity of the air quality problem, however, apply only to ozone, not to particulate matter. Given the significant unknowns (where, how much, from what sources) with respect to PM_{2.5}, we are concerned about deadlines and the consequences of failure to meet them in however many areas may be out of compliance.

Despite Administrator Browner's assurances in her recent testimony before your committee that 70 percent of the potential nonattainment areas can come into compliance with the proposed new standards by using existing technology and strategies, we question the validity of this assumption and furthermore, are concerned about the remaining 30 percent.

JUDICIAL INTERVENTION

As public officials, I must say we find it peculiar that, more often than not, EPA complies with its legal deadlines, obligations and requirements only in response to lawsuits and court orders. In some respects, we empathize with EPA; they too must deal with "unfunded Federal mandates." However, we too have inadequate resources to accomplish all that is required of us. I cannot imagine a circumstance in which a municipality could simply ignore a legislated requirement for almost 20 years without consequence.

Court driven decisions, with unrealistic deadlines, on complex environmental issues are not helpful. It is incredibly frustrating to read the Clean Air Science Advi-

sory Committee's letter with respect to PM_{2.5} which says, ". . . the deadlines did not allow adequate time to analyze, integrate, interpret, and debate the available data on a very complex issue." (see CASAC letter to Administrator Browner dated June 13, 1996, page 3).

RECOMMENDATIONS

First, we do not believe the courts should be permitted to force decisions on complex scientific matters. At a minimum, Congress should overturn the court's deadline giving EPA and the scientific community adequate time to draw sound scientific conclusion about further reductions in air emissions.

Second, EPA should be required to obey the laws applicable to the agency just like everyone else. But, Congress must also assure they have the resources to do so. If the Clean Air Act requires EPA to review air pollution standards every 5 years, the funding to comply with this requirement should be provided. If these funds are unavailable—because of limited Federal resources or alternative national priorities—then this requirement should be changed accordingly.

Third, if indeed, as Administrator Browner indicated in your recent hearings, over 200 scientific studies support the need for tighter controls on specific air emissions, then EPA has done a poor job of publicizing, explaining or demonstrating the adequacy of the scientific basis for their proposals. No one expects unanimity on complex science, but the American people need far better assurances than they have now that the scientific basis for these proposals is sound. We either need more and better science, or more and better explanations that the science that exists is valid.

Fourth, before moving forward with ever more stringent requirements, the impact of implementing new requirements in the State implementation plans that have only recently been approved needs to be assessed. No new standards should be imposed until such assessment has occurred.

And finally, we need better information about the pervasiveness of PM_{2.5} before proposals are finalized. How many PM_{2.5} non-attainment areas are there; where are they located; and how significant is the problem in these areas. It is difficult to accept that a problem exists if there is little information about where it exists.

Mr. Chairman, members of the Committee; thank you for the opportunity to testify on this important issue to the nation's cities and towns. I would be happy to answer any questions I can.

RESOLUTION—No. 97-7

PROPOSED CHANGES IN CLEAN AIR ACT STANDARDS

Whereas, the U.S. Environmental Protection Agency has proposed new standards for ozone and particulate matter; and

Whereas, these new standards could have a significant impact on local governments, substantially expanding the number of areas out of compliance with the National Ambient Air Quality Standards; and

Whereas, full implementation of the existing standards for ozone has not yet been fully completed; and

Whereas, EPA is proposing significant new monitoring requirements to determine whether and where there is a problem with respect to the proposed new standard for particulate matter; and

Whereas, there is scientific uncertainty as to whether particulate matter (regulated at 2.5 microns) or a constituent comprising PM_{2.5} (sulfur dioxide, nitrogen oxide, volatile organic compounds) is a health risk; and

Whereas, court-ordered deadlines to resolve issues involving complex scientific matters are inappropriate; and

Whereas, because of the court ordered deadline, the comment period of these proposals will be limited to sixty days from publication in the Federal Register;

Now Therefore Be It Resolved, That the National League of Cities calls on the U.S. Congress to:

- reaffirm the existing standard for ozone to allow sufficient time to assess the impact of the current pollution control programs before imposing more stringent requirements;
- overturn the court-ordered deadlines for the issuance of new standards for particulate matter; and
- require EPA to conduct adequate and appropriate monitoring and scientific research to assure that any new standards for particulate matter are based on sound scientific information.

Be It Further Resolved, That NLC urges Congress to ensure that EPA has adequate time to consider all relevant evidence in revising air standards and that the Agency not be forced to promulgate new and costly standards prematurely because of arbitrary court-ordered deadlines.

PREPARED STATEMENT OF MAYOR PATRICK HENRY HAYS, NORTH LITTLE ROCK, AR

I am pleased to be on this panel. My name is Patrick Henry Hays. I am Mayor of the city of North Little Rock, Arkansas. Mayor Jim Dailey of Little Rock was originally slated to be here, but circumstances prevented him from attending. He extends his warm regards and sincere interest in this topic of vital interest to all in central Arkansas.

If I may, I would first like to say a few words about North Little Rock, our regional planning agency and the central Arkansas area, which I am here representing. North Little Rock is located across from Little Rock on the Arkansas River. We are a community of approximately 65,000 persons and a destination for many others who work or shop in our city. The air quality monitors that are used to determine violations of the ozone standard in central Arkansas are located in North Little Rock.

North Little Rock is a member of Metroplan, which is a council of local governments and the designated metropolitan planning organization, or MPO, for the Little Rock-North Little Rock Metropolitan Statistical Area (MSA). Metroplan has twenty-two (22) member governments, plus the Arkansas State Highway and Transportation Department (AHTD), and the Central Arkansas transit Authority (CATA). Metroplan is an example of the cooperative spirit that has developed in central Arkansas among elected officials and other community leaders in the area.

Little Rock is the State Capital and located approximately in the geographic center of the State. Our region is also located at the center of the State's transportation and distribution network. It is the largest metropolitan area in the State, with over 550,000 residents and over 300,000 workers. Our economy is healthy and growing. Employment in the four-county area is concentrated in the services (29 percent), trade (24 percent), and government (19 percent) sectors. During the 5-year period between 1990 and 1995, total MSA population grew by 5.3 percent, while employment increased 11.3 percent.

Now regarding the air quality in central Arkansas, we have been in attainment of all national ambient air quality standards (NAAQS) since 1983. However, there have been several exceedances of the ozone standard, although these have been such rare events that our attainment status has remained unchanged. Even without the control measures that could have accompanied nonattainment, we have seen a general reduction in our ozone levels during the last 10 years. We mainly attribute this to turnover in the vehicle fleet, wherein newer cleaner vehicles have gradually replaced older more polluting vehicles. Somewhat milder summer temperatures may have also helped to improve our air quality in recent years. Violations of the particulate matter standards have not even been an issue, since the PM₁₀ standards were adopted in 1987. In recognition of our clean air status, approximately one and one-half years ago an areawide coalition of alternative fuel and clean air stakeholders was put together, which led to our designation by the U. S. Department of Energy as the Central Arkansas Clean Cities Area. Data and charts illustrating the air quality history of central Arkansas are attached to my written statement.

Since EPA proposed changes to the ozone and particulate matter standards, at least two sets of comments have been adopted by community leaders in our area.

On February 24, 1997, the North Little Rock City Council adopted a resolution urging Congress to retain the existing national ambient air quality standards for ozone and particulate matter. We indicated that the impact of the current standards and control programs should be assessed before imposing more stringent requirements. Our resolution also urged Congress to overturn the court-ordered deadlines for promulgation of new particulate matter standards, and indicated that BPA should first institute adequate and appropriate monitoring of fine particulates before promulgating any new standards for PM_{2.5}. A copy of the resolution is attached to my written statement.

Last week, on February 26, 1997, the Metroplan Board of Directors unanimously approved comments regarding EPA's proposed air quality standards for both ozone and fine particulate matter. While Metroplan's comments are attached to my written statement, I would like to briefly summarize them here.

With respect to the proposed ozone standard the Metroplan Board's comments indicate that:

- We can support an 8-hour concentration based standard, because it is more directly associated with the health effects cited in exposure studies and there is scientific agreement on this issue.

- The conventional rounding convention should be maintained with respect to determining violations, due to the same data accuracy concerns that CPA has cited in their proposals.

- We do not support EPA's proposal to use the average third-highest daily maximum, set at 0.08 parts per million, because the Clean Air Scientific Advisory Committee could not achieve a consensus on either the appropriate level or form for an 8-hour standard.

- We believe that an 8-hour ozone standard would afford improved protection over the current standard for persons at risk if based on either the third-highest daily maximum set at 0.09 parts per million or the fifth-highest daily maximum set 0.08 parts per million.

With respect to the proposed PM-2.5 standards the Metroplan Board's comments indicate that:

- At present, there is no monitoring program for PM-2.5 and very little data regarding the extent and sources of PM-2.5. This is problematic for a variety of reasons. For example, if natural sources are a major component of PM-2.5, controlling man-made sources may not be an effective approach. In addition, what if all metropolitan areas or large agricultural districts or national forests were designated in nonattainment of the PM-2.5 standards?

- Nonattainment of the proposed PM-2.5 standards could severely impact metropolitan areas, due to the connection between the Clean Air Act Amendments and ISTEA. For example, areas designated in nonattainment would have limitations on the type of transportation projects that could be implemented. MPOs would also have to prove "conformity" with the State Implementation Plan (SIP) for air quality control, before most projects would be approved by EPA. This would result in more project delays and increase both MPO and project costs. In addition, limited or reduced Federal funding for public transit conflicts with more restrictive air quality standards, in that transit may be one of the major strategies for reducing emissions from mobile sources.

For these reasons, we think that fine particulates should be monitored by all States for a period of up to 3 years without regulation consequences to determine the extent and sources of PM-2.5. Afterwards, the standards should be subject to another public comment period. This decision on fine particulate standards should not be made without better data and understanding of the likely consequences.

In conclusion, it is fair to say that we are concerned about the consequences to our State and regional economies, if EPA's proposed changes are allowed to go into effect. The possibility exists that central Arkansas and West Memphis could be designated in nonattainment of the proposed ozone or particulate matter standards. Currently, businesses are attracted to central Arkansas and to our State, partly because we are in attainment of the clean air standards. If our clean air status changes our ability to attract new industry could be undermined, and perhaps, even some existing industry and jobs could be lost as well.

I ask that my written statement and attachments be placed in the official record of this hearing. I will attempt to respond to any questions you may have. Thank you!

PREPARED STATEMENT OF RONALD F. HAMMERSCHMIDT, DIRECTOR, DIVISION OF ENVIRONMENT, KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

We are pleased with the opportunity to provide comment on the revisions proposed by the U.S. Environmental Protection Agency (EPA) to the National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter. The Kansas Department of Health and Environment has a critical interest in the proposals both as an agency responsible for implementing many of the air quality programs affected by the proposals, as well as the state-level agency in Kansas responsible for developing and implementing statewide programs designed to protect the public health in our State. It goes without saying, that the protection of the health of the citizens of Kansas is of paramount importance to our agency and our State. On this basis, our comments are presented primarily from the perspective of an implementing agency. The health effects research referenced by the EPA has not been the subject of critical review by our agency.

The State of Kansas is proud of its air quality and recognizes the importance of clean air to the health of its citizens, its environment, and its economy. Kansas is currently attainment for all ambient air quality standards statewide. Past successes

are attributed to the ability of local, State, and Federal Government agencies across the State to work effectively with affected business interests, special interest groups, and the general public to promote improvements in air quality. These relationships are critical to continued success in our air quality programs.

Although many questions remain relative to the technical requirements and implementation costs for these complex proposals, our most fundamental concerns lie in two areas.

The first of these involves the shortage of information and apparent inconsistencies in that information which is available on the characteristics and origins of the particles targeted by the proposal to establish a new fine particle particulate matter (PM_{2.5}) standard. The particles of greatest concern are being distinguished from the coarse particles currently regulated on the basis that they are characteristically different (e.g., combustion-related, soluble, chemically-reactive, etc.) and that they originate from different sources including processes that result in the formation of *secondary* particles from gaseous precursors. However, emission information pertaining to the sources of *primary* PM_{2.5} particles indicates that a significant overlap occurs between the fine and coarse fractions of many sources of fugitive dust; including paved roads, unpaved roads, and windblown dust. This confusion has been exacerbated by the lack of PM_{2.5} air monitoring data in rural States. As a result, the fugitive dust component of PM_{2.5} emissions in the rural areas of the United States may represent a source of exposure not intended to be implicated as a target of concern by the health studies completed primarily in the larger urban areas of the United States. It seems apparent that adequate study has not been completed of the sources and health implications of exposure to PM_{2.5} particles in rural areas. Because of these concerns, our agency will be providing comment to EPA that additional speciated air monitoring information be collected to assess the role of fugitive dust in the PM_{2.5} standard proposal and to more accurately characterize the particles of concern. Ideally, this information would be available prior to final decision-making on the new particulate matter standard.

Our second major area of concern involves the potential impact of the proposed revision to the ozone standard in Kansas City. Historically, ozone has been a concern in Kansas primarily in the metropolitan area of Kansas City. A five-county area in Kansas City (including Johnson and Wyandotte counties in Kansas) was declared an ozone nonattainment area in the late 1970's and remained as such until 1992 when the area was federally-approved for redesignation to attainment. In order to gain attainment status, the States of Kansas and Missouri were required to demonstrate to EPA that compliance with the standard could be maintained into the future and a long-term maintenance plan was approved. Hot weather conditions experienced during the summer of 1995 resulted in a total of nine exceedances of the standard spread across four of the six ozone monitoring sites maintained throughout the five-county area. These exceedances resulted in a regulatory violation at one of the monitoring locations. The resulting violation triggered implementation of contingency provisions in the maintenance plan designed to respond to future findings of air quality problems. This response was organized through a regional air quality forum consisting of a broad coalition of interested parties including State, local, and Federal Government representatives, local businesses, environmental groups, and members of the public. A series of recommendations for enhancements to the emission control, transportation management, and air-related public education programs in Kansas City emerged from this group. These recommendations include actions above those required as the minimum in the maintenance plan approved for the area. Forum members arrived at a clear consensus that continued progress to prevent further air quality problems in Kansas City was in the best interest of the city now and in the future. State and local governments (including the regional planning organization) are currently preparing plans and adopting regulations to implement the recommendations of the Kansas City air quality forum.

Although air quality progress continues in Kansas City under its current maintenance plan, the proposed revision to a 0.08 ppm (eight-hour average, third high) standard will result in the return of the Kansas City area to nonattainment status. By way of comparison to the existing standard, the excursions during 1995 resulted in a total of 3 days of air quality problems. If the revision proposed had been in effect in 1995, the area would have experienced a total of 17 air quality problem days. Compliance with such a standard will be very difficult. If the lower range proposed (0.07 ppm, 8-hour average, first high) had been in effect, a total of 31 problem days would have occurred. Even the highest range proposed (0.09 ppm, 8-hour average, fifth high) would have increased the number of problem days in 1995 from three to seven even though the 0.09 ppm proposal is presented as being roughly equivalent to the current standard.

While we believe the scientific advisers to EPA, and the EPA itself, should be applauded for openly acknowledging their difficulties in arriving at a single, discrete level for a revised ozone standard, the differences in the impact to implementing agencies (and associated health implications) between a 0.07 ppm standard and a 0.09 ppm standard are pronounced in Kansas. The lower range proposed (0.07 ppm, 8-hour average, first high) has been exceeded in far western Kansas in a rural community with a population of 4,800 residents.

Despite the wide range of numerical options presented in the proposal, the recommended level of 0.08 ppm (third high) creates a discrete regulatory compliance level that will have significant impact in Kansas City. As noted previously, the attainment status of the area would most certainly return to nonattainment at a time during which a broad community effort was encouraging additional air quality control measures well above the minimum required under the area's maintenance plan. The current impetus for these actions has been the community consensus to make a "clean" city cleaner. Upon return to a nonattainment status, there is great concern that the impetus will change to one that attempts to make a "dirty" city cleaner. This shift from a community process to a regulatory process may reduce the value of community involvement in the implementation of air quality initiatives when faced with new regulatory agency mandates. We have deep concerns that this change will polarize affected interests and delay further progress in Kansas City. Delays in actual air quality improvements may also occur as a result of implementing agencies having to begin a new, extended planning process including modeling and attainment plan development. The timeframe for developing a new attainment plan will be long in comparison to the much shorter timeframe involved in continuing progress under the maintenance process. The depth of the impacts of the proposed 0.08 ppm standard in Kansas City has prompted our agency to prepare comments for submittal to EPA that encourages retention of the existing standard until the attainment/nonattainment designation process can be reformed. Such reforms would recognize the uncertainties involved in establishing a discrete ozone compliance level and the value of establishing a tiered regulatory approach.

Again, we appreciate the opportunity to bring this information before the Subcommittee.

PREPARED STATEMENT OF BARRY R. MCBEE, CHAIRMAN, TEXAS NATURAL RESOURCE CONSERVATION COMMISSION

Thank you very much for inviting me here today to offer testimony on this vitally important issue for Oklahoma, for Texas and for all of our States.

For the record I need to clearly express that these are my personal comments as chairman of the State's environmental agency, but not yet the official agency policy—a policy that will be voted on and finalized later next week.

Also for purposes of the record it is important to note that we in Texas felt it was important to solicit public input on these new proposed standards. In January and February we held nine public meetings across the State and heard from hundreds of citizens. In total, we received more than 2,200 comments.

Everyone in this room supports clean air. The good news is that ozone levels in our State are dropping and our standards and controls are having the desired impact. We in Texas, while making progress, have been waiting like other States for these new EPA standards to be announced, hopeful that they would be a clear mandate fully supported by the scientific community. That is not what happened.

It should not be too much to ask government, especially given the potential effects on families, business and industry and lifestyles and the staggering cost of many regulations, to adopt standards that are both clear and based on sound and complete science. With so much at stake, the Federal Government simply is not doing its job if these standards are not clear and not built on that basis.

Sadly, however, these proposals from EPA have not established the "bright line" about where the standards should be. And, in my opinion, there have to be bright lines for these standards. Instead, I—as an environmental policymaker in a State in which more than 18 million people live, and with untold billions of dollars at stake—am forced to make decisions in the midst of a gray area of science, where everyone agrees that nothing is certain and not enough is known. We don't have bright lines. At best we have only dim ones. We have educated guesswork—and for our citizens that is clearly not enough.

Some of you may be familiar with a recent study sponsored by EPA—a study which Texas was not notified about before it appeared on the Internet—that has increased the uncertainty about replacing the 1-hour ozone standard with an 8-hour

standard. The study seems to suggest that the 1-hour standard would be more protective than the 8-hour standard in two cities, Houston and Los Angeles.

This has contributed to the atmosphere of confusion which already exists about this whole process. It clearly points out that we do not know as much as we think we do about ozone. Surprisingly, we do not know enough even about the two cities with the worst problems in the country. We have to know more.

Because of this, the EPA proposals on ozone and particulate matter should be separated. And in light of this new EPA study alone, it is not good public policy to act now to change the ozone standard. EPA was compelled by the courts to move on the particulate standard. That is not the case for ozone, but EPA chose to proceed at the same time. If more research is needed on ozone, we should do that now instead of prematurely altering a standard which, I will remind you, is working in Texas.

And yet another compelling reason to separate the issues is the cost to society of these new ozone standards which E.P.A.'s own studies have indicated will be significant.

This EPA study also points out another problem. If research shows that different areas of Texas should have different standards to protect their citizens, how can EPA still maintain that "one size fits all?" EPA in this study itself has pointed out that what is good for Dallas/Fort Worth may not be good for Houston—and the State of Texas should not therefore be forced to enact a State standard on top of the Federal standard to fix what EPA refuses to fix. It should be clear that one size may not fit all, and that it may be time for a flexible, regional approach to clean air and air standards. It should be possible under EPA guidance for regions to select controls, based on research, that will do the most to clean up their air.

If, however, the EPA decides to move forward with its ozone proposal with a level of .08 ppm—perceiving that somehow as the bright line for the Nation—please let me tell you that the line is in the wrong place. There is no consensus. EPA chose .08 even though the range of .08 to .09 ppm or higher was recommended by more of EPA's own Clean Air Science Advisory Committee members who expressed an opinion on a specific standard. And there is no toxicological study which shows more health protection from a .09 level than one of .08.

Given that, setting the allowable ozone level thus becomes a matter of public policy. And I believe the right policy decision is one that does not, as the .08 proposal does, boost the number of nonattainment areas in Texas from four to nine—more than any other State. That standard might not ever be attained by some areas, regardless of the level of controls. And all of this in the context of EPA's admission that we don't know what we thought we knew about ozone in the Houston area.

As I mentioned earlier, the levels of ozone in our State have seen a general decline. We can point to hard data, for example, that show ozone levels in the Dallas/Fort Worth nonattainment area are decreasing and that specific controls are working. But if the standard is changed in midstream, at what cost to DFW and other areas do we do so? And do we know that the new standard—given the uncertainties from studies like the one I've mentioned, from ongoing studies about ozone transport and other issues—will work better in DFW or any area in Texas? We do not.

On other aspects of the ozone proposal, I do believe that those areas that have worked hard for flexible attainment region status—including Tulsa, and two areas in my State, Corpus Christi and Longview/Tyler/Marshall, should be given time to let their strategies work.

In reference to the interim implementation policy proposal we support the following points: spatial averaging; the need for greater communication of ozone highs, especially to populations sensitive to ozone; and the need to have incentives for early emission reductions. And one final point, we need agreement that there is no need to keep working on the premise of a 1-hour standard if this will be changing, so we should refocus our resources toward a new standard.

As for particulate matter, we have gone from ozone's dim line to no line at all. There are very few data on fine particulate matter and, based on what EPA is proposing, absolutely no data from monitoring in Texas. There does appear to be a growing body of evidence that there could be long-term health effects from fine particulate matter. But CASAC, which expressed concern about potential health effects, was not even close to a consensus on a standard; it expressed instead legitimate concerns and unanswered questions. What we have to do instead of setting a premature standard is to speed up dramatically the Federal research efforts, which CASAC and the Western Governors Association have called for, and only after that research has concluded decide on a standard, if any.

Also, I would ask members of this Committee to press for review of these proposals under the Small Business Regulatory Enforcement Fairness Act (SBREFA). Although EPA may say that the proper time for this review is at implementation of

these standards, if and when that happens, that will not work. The standard will be implemented not by EPA but by the 50 States and at different paces.

Finally, in this time when our citizens expect fiscal responsibility and reject incomplete science, we should very carefully consider any legislation which does not require a very formal and careful assessment of actual costs compared to proven benefits. As in the case of these standards, citizens have every right to expect a bright line about sound science and costs vs. benefits, not educated guesswork.

PREPARED STATEMENT OF J. DALE GIVENS, SECRETARY, LOUISIANA DEPARTMENT OF ENVIRONMENTAL QUALITY

Good afternoon. My name is J. Dale Givens and I am the Secretary of the Louisiana Department of Environmental Quality. Thank you for allowing me the opportunity to provide testimony on the proposed changes to the National Ambient Air Quality Standards for ozone and particulate matter.

Louisiana, in partnership with the Environmental Protection Agency (EPA) has been very successful in improving air quality through the implementation of the Clean Air Act. Today Louisiana meets five of the six National Ambient Air Quality Standards (NAAQS) for criteria pollutants with only ozone remaining. Our ozone nonattainment parishes have decreased from 20 to 5. We have met our obligations under the 1990 amendments of the Clean Air Act (CAA), completing all required emission reductions. We have submitted the required ozone attainment demonstration plan. As required by the CAA, complete implementation of the attainment plan will be accomplished in 1999. At that time, we expect to be in full compliance with the present ozone standard. Already, as a result of substantial emission reductions in place, air monitoring data show marked decreases in ozone. Louisiana is on a successful course for cleaner air.

Louisiana supports the establishment of National Ambient Air Quality Standards (NAAQS) which are necessary to protect human health and which are based on sound technical and scientific data. In the setting of the standards, the EPA has stated that it cannot consider economic or technological feasibility of attaining the standard. We have therefore concentrated our review of the proposal based on the underlying health science including the EPA staff paper and the independent scientific advisory reports. Based on our study of these documents, Louisiana supports the EPA position that an 8-hour standard is more appropriate for a human health-based standard than the present 1-hour standard. Louisiana also agrees that the form of the standard should be concentration based.

The EPA's staff paper recommends 0.09 ppm as the upper level of an 8 hour standard that would reduce estimated exposures of the at risk populations sufficiently to provide some margin of safety against pulmonary inflammation and increased susceptibility to pulmonary infection. Louisiana supports a level of the standard set at 0.09 ppm as the 3 year average of the annual third highest maximum 8 hour average ozone concentration. As we appreciate the underlying science for setting the new standard, little or no public health benefit would be gained by setting the standard at 0.08 ppm rather than 0.09 ppm.

In addition, Louisiana favors the proposal made by a number of CASAC members for an expanded air pollution warning system which could be implemented for sensitive individuals who could then take appropriate exposure avoidance action. CASAC pointed out to the EPA that this idea would be easy to implement since many areas of the country already have an infrastructure in place to designate ozone action days when voluntary emission reduction measures can be taken. Tulsa Oklahoma already has such a program in place. For a number of years the Baton Rouge area has operated a program to apply administrative emission controls to industrial sources during periods when ozone levels are expected to be elevated. Efforts to develop a community ozone action day program were begun last summer in Baton Rouge. This effort is expected to continue this summer and is supported by the public.

These are our initial comments regarding the primary standard being proposed for ozone. We are continuing to review the entire proposed set of changes which includes the secondary standard for ozone, the changes to the particulate matter standard and the implementation proposal for both pollutants. Due to the large volume of documentation associated with these proposals, it will take time to properly review them and the support documentation in order to provide additional comments.

Thank you for the opportunity to comment and your attention to the concerns of Louisiana.

PREPARED STATEMENT OF RICHARD E. GRUSNICK, DEPUTY DIRECTOR, ALABAMA
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

Mr. Chairman and members of the subcommittee, good morning. My name is Richard Grusnick and I am deputy director of the Alabama Department of Environmental Management, the agency charged with administering the major environmental laws in Alabama. Prior to assuming my current duties, I was chief of the department's air division and have been involved in Alabama's program to regulate air pollution since its inception in 1972.

I appreciate the opportunity to appear before this subcommittee today as it conducts oversight hearings on EPA's recent proposal to revise the air quality standards for ozone and particulate matter and the effect these proposals may have on State and local governments. There are two basic points I wish to make today. These are:

1. Tightening the standards would divert regulatory resources from the areas with the most serious air quality problems.

2. Given the difficulty and resistance encountered in identifying and implementing the measures required to meet the current air quality standards, the credibility of all levels of government may ultimately decline if the proposed standards are adopted.

The only current nonattainment area in Alabama is the Birmingham area which includes Jefferson and Shelby counties. Birmingham was designated a marginal ozone nonattainment area pursuant to the Clean Air Act amendments of 1990. A significant amount of the air regulatory resources in the State have been focused in this area by developing and enforcing regulations dealing with smaller sources than are regulated in the remainder of the State and by working with the transportation planning agencies to ensure that transportation improvement plans conform with the air quality goals in this largest metropolitan area of the State. This makes sense—focus the regulatory efforts and associated increased costs in the area of the State with the worst air quality where the benefits would be greatest. This focusing of resources would decrease if the proposed standards were adopted.

Under the range of proposed standards, the number of nonattainment counties in Alabama would increase from two to somewhere between eight and all sixty seven counties, with the most likely scenario including a minimum of 20 counties. It is not realistic to expect that resources available to the regulatory effort would increase to correspond with the increased workload of developing the necessary plans, regulations and implementing the requirements in each of the counties. This would mean that resources would have to be diverted from the areas with the most severe air quality problems to implement the requirements in the newly designated, less severely impacted, less densely populated nonattainment areas. Given the reality of limited resources, I question whether establishing a tighter standard will actually result in the most effective use of State resources to provide the maximum benefits from cleaner air in Alabama.

I also have reservations about the continued credibility of efforts to improve air quality. The days of easy choices have passed. This was evidenced by the 10 years it took Congress to reauthorize the Clean Air Act with the 1990 amendments and the challenges already faced in implementing its provisions. No longer are requiring controls on large industry and the manufacture of lower emitting new vehicles adequate to satisfy the air quality mandates of the existing law. Small businesses are now required to reduce their emissions and lifestyle changes are necessary in some areas. I have seen presentations by representatives of other, more challenged States which indicate emission reductions in excess of 70 percent will be required to meet the *current standard*. Couple this with the fact that transportation sources are generally responsible for half the emissions and the problem is obvious. Many of the more severely impacted areas have been unable to develop plans to meet the *current standard* using any politically or socially acceptable strategy. Investigations into long range transport have also failed to identify a strategy which would allow the current standard to be achieved throughout the eastern U.S. From a practical perspective, I think it is reasonable to question "raising the target" when the current one is already too high to hit in many instances.

In addition, many of the measures recently implemented have met with strong opposition. In the more severely impacted areas smaller businesses have been regulated, automobiles now have their emissions tested, and certain types of new industrial growth continues to be essentially precluded by the emissions "offset" requirements. Tightening the air quality standard would significantly expand the number of areas subject to these requirements and may undermine the support for continued air quality improvement. This is especially likely since these requirements will

impact more rural areas which have traditionally been viewed as having good air quality.

It should also be noted that continued improvement in air quality will occur even absent a revision to the standards since the aggressive requirements of the Clean Air Act amendments of 1990 contain many far reaching emission reduction provisions which have not yet been fully implemented. Many of these provisions will result in significant reductions in the emissions of pollutants responsible for ozone and fine particulate matter. Perhaps continued evaluation of the disputed health effects studies would be reasonable as we continue to implement the blueprint for improving air quality established by Congress in the 1990 amendments.

In summary, adoption of the proposed standards would most likely result in:

- diverting regulatory resources from the most impacted areas; and
- a loss of government credibility.

All the while air quality improvements will continue to be realized as a result of the 1990 amendments.

PREPARED STATEMENT OF MARK S. COLEMAN, EXECUTIVE DIRECTOR, OKLAHOMA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Thank you for the opportunity to testify on issues that are of great importance to the citizens of Oklahoma and the Nation. On behalf of the citizens of the State of Oklahoma, I wish to submit the following remarks: Under the current Ambient Air Quality Standards, the entire State of Oklahoma is considered to be in attainment status. In many respects our State has been an innovator in the field of air pollution control. Oklahoma was the first State to institute ozone and carbon monoxide alert programs. These programs were further enhanced by the adoption of the flexible attainment region program for the metropolitan areas of our State. The programs have become "blueprints" for numerous other areas of the country. Industry, the general public, as well as government have striven to maintain our clean air status, and we are justifiably proud of these efforts. These advances have come at no small effort on the part of our citizenry. Many changes have been made on a voluntary basis which have maintained the clean air we currently enjoy. With many of the effects of the 1990 Clean Air Act amendments unclear and yet to be realized, it would seem imprudent to make wholesale changes at this date.

However, if the standards are to be changed, the existing body of scientific data seem to indicate that the standard for ozone should be set on an 8-hour basis, which for the majority of the country is more protective of human health. For those areas where this may not be the case, the secondary standard set at current levels should be maintained. The numerical level of the standard could be set at a level close to that of the current standard until such time as the scientific evidence demonstrates a level which meets the "bright line" test. Such a strategy would allow for the protection of those who are exposed over a long period of time and would allow for the further collection of scientific data upon which to base changes to the ozone standard. The actual statistical treatment of the data should allow for the atmospheric abnormalities which occur frequently during the ozone season.

The new proposal for the particulate standard needs to be looked at in the light of the actions that are available to the agency. The preponderance of scientific data seem to indicate that these smaller particles are more dangerous to human health than those we currently regulate. It appears that much of the data upon which the conclusions were based are data which has been extrapolated from other data sets developed from larger particles. Since one of the actions available to the agency is to reaffirm the current standard and mandate the collection of actual data upon which decisions can be made, perhaps that option should be pursued. The shortage of reliable consistent, quality assured data about these small particles and their origins is of the utmost importance before we move forward with the standard setting process. Since these particles are not well understood, and since there is evidence which indicates that there is some overlap between fine and coarse fractions further research must be undertaken to describe the interactions between the particles and their gaseous precursors.

It seems apparent that the research necessary to understand the public health impacts, the sources of these particles and the implications of exposure to the various levels of fine particles needs further refinement. Since the particles in question, are of various species, we strongly recommend further collection of speciated data to characterize the particles of concern.

While we understand the process EPA and its advisors have undertaken, the record of these deliberations themselves indicate that there is not a strong body of evidence which leads us to a single discrete level at which to set either standard.

The advisory body as well as the EPA staff are to be commended for their efforts. However, in the light of the costs associated with the setting of either of the proposed standards as well as the impact on the implementing agencies, we have grave concerns that actions which are not well founded nor based on clear and compelling scientific data may actually cause a backsliding in Oklahoma's support of Air Quality improvements. Again, thank you for the opportunity to testify.

